

Labex.



Laboratoire d'Expertise Clinique Espagne S.A.U.

Study report

for : **INDUSTEX, S.L.**



Efficacy

Date :17/01/2020.....

N° :E190477.....

www.lab-ex.org

CONFIDENTIAL

REPORT : OBJECTIVATION STUDY**REDUCING EFFECT AND CELLULITE IMPROVEMENT**

CLINICAL STUDY FOR THE EVALUATION OF THE REDUCING EFFECT AND CELLULITE IMPROVEMENT OF A COSMETIC INVESTIGATIONAL PRODUCT, APPLIED UNDER NORMAL CONDITIONS OF USE, FOR 4 WEEKS, IN FEMALE ADULT SUBJECTS

INVESTIGATIONAL PRODUCT : **VELFORM CELLU WRAP (ref.: LOGIC: VCSVFFSET0254)**

LABEX PRODUCT CODE : E190477 062021

EXPERIMENTAL PROTOCOL N° : E190477PE version 1, of 12 November 2019

REPORT N° : E190477RD version 1, of 17 January 2020

START OF OBSERVATIONS : 20 November 2019

END OF OBSERVATIONS : 18 December 2019

| STUDY MONITOR | RESPONSIBLE FOR THE STUDY |
|--|---|
| E. SOUTO INDUSTEX, S.L. Av. Paisos Catalans, 34 – 8ª Planta 08950 ESPLUGUES DE LLOBREGAT | B. RAIS Ph.D. Biological and Medical Sciences European Registered Toxicologist - EUROTOX LABEX. Passeig Sant Joan, 76 08009 BARCELONA |

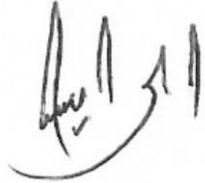
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A U T H E N T I C A T I O N

The study purpose of this present report was conducted under my responsibility, in compliance with the experimental protocol and in accordance with Labex Standard Operating Procedures, and according to the spirit of the general principles of the Good Clinical Practices.

All observations and numerical data obtained during this study are reported in the present document.



Badr RAIS
Technical Manager

Q U A L I T Y C O N T R O L

This study was performed in conformity with the Standard Operating Procedures of the Laboratoire d'Expertise Clinique Espagne, the protocol signed with the sponsor and "in the spirit" of the general principles of the Good Clinical Practices published by I.C.H. (Topic E6 : CPMP/ICH/135/95).

Audits of clinical studies are conducted every 6 months for each type of study. They are intended to check the correct application of the procedures during the study. The results of these audits are subject to reporting to the Investigator, the Technical Responsible and the Responsible for the Study.

Labex. Quality Unit confirms the compliance of this report with the data generated during the study.

Barcelona, 17 January 2020



Amina RADI
Auditor Quality

| P R O T O C O L | | | | | | | | | |
|---|---|------|--------------------------|------------------------|--|------------------------|--|---|--------------------------|
| <u>STUDY OBJECTIVE</u> | To assess the reducing effect and cellulite improvement of an investigational product, by measuring weight and centimeter measurements at the level of the abdomen, thighs and hips perimeter and by clinical scoring by the subject and the investigator of the degree of cellulite, before the use, during and after 28 days of daily use, under the normal conditions of use, in female adult subjects. Claims to justify: "Reducing effect" and "Cellulite improvement". | | | | | | | | |
| <u>TYPE OF STUDY</u> | Objectivation study: Reducing effect and Cellulite improvement | | | | | | | | |
| <u>STUDY RELEVANCE</u> | Evaluation based on: <ul style="list-style-type: none"> - Centimeter measures - Weight measures - Clinical visual scoring by the subject and the investigator - A questionnaire adapted to the studied product | | | | | | | | |
| <u>INCLUSION CRITERIA</u> <i>(in addition to the standard criteria of Labex.)</i> | <ul style="list-style-type: none"> . Number of subjects : 20 . Sex : female . Age : 18 to 60 years old . Origin : caucasian . Body skin type : indifferent . Other : subject with BMI 24 to 32 . Other : subject with cellulite . Sensitivity of skin : maximum of 50-60% being considered sensitive the subjects that have a recent history and repeated functional symptomatology of skin discomfort (ex. tingling, stiffness, warmth, stinging, burning, redness ...) . Healthy subjects with atopy background: 20-25% maximum: currently admitted proportion for the Spanish population | | | | | | | | |
| <u>METHODOLOGY</u> | <p>Modalities application of the investigational product</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Area</td> <td>Abdomen, thighs and hips</td> </tr> <tr> <td>Frequency and duration</td> <td>Twice a day (morning and night) , during 4 weeks</td> </tr> <tr> <td>Application conditions</td> <td>By the subject herself, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions: <i>Apply the cream twice a day (morning and night), in the areas to be treated (abdomen, thighs and hips) with circular movements, by means of a soft massage until the product is completely absorbed. The pants should be worn at night. Set accompanied by a diet.</i></td> </tr> <tr> <td>Concomitant application of other products</td> <td>Usual cleansing products</td> </tr> </table> <p>Modalities of evaluations</p> <ul style="list-style-type: none"> ☞ Objective determination of the reduction effect by comparison: <ul style="list-style-type: none"> - D1 : before using the research product. - D8 : after 7 days of use of the investigational product, normal daily activities and following the diet - D29 : after 28 days of use of the investigational product, normal daily activities and following the diet. ☞ Measurement of the weight of each volunteer at D1, D8 and D29. ☞ Centimeter measurements at the level of abdomen, thighs and waist perimeter, where the subject has a higher concentration of fat, at D1, D8 and D29. The measurements were done in air-conditioned room at a constant temperature of 21 ± 1°C and controlled relative humidity. | Area | Abdomen, thighs and hips | Frequency and duration | Twice a day (morning and night) , during 4 weeks | Application conditions | By the subject herself, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions: <i>Apply the cream twice a day (morning and night), in the areas to be treated (abdomen, thighs and hips) with circular movements, by means of a soft massage until the product is completely absorbed. The pants should be worn at night. Set accompanied by a diet.</i> | Concomitant application of other products | Usual cleansing products |
| Area | Abdomen, thighs and hips | | | | | | | | |
| Frequency and duration | Twice a day (morning and night) , during 4 weeks | | | | | | | | |
| Application conditions | By the subject herself, at home (starting on D1 and ending on D28), under the normal conditions of use, following the Sponsor's instructions: <i>Apply the cream twice a day (morning and night), in the areas to be treated (abdomen, thighs and hips) with circular movements, by means of a soft massage until the product is completely absorbed. The pants should be worn at night. Set accompanied by a diet.</i> | | | | | | | | |
| Concomitant application of other products | Usual cleansing products | | | | | | | | |

| | |
|-----------------------------|---|
| <u>METHODOLOGY</u> | <p>☞ Visual scan by investigator and subject at D1, D8 and D29 at abdomen, thighs and hips level. Scoring by means of the Nürnberger-Müller 4-point visual scale:</p> <ul style="list-style-type: none"> ☞ Type I: No skin surface alterations; ☞ Type II: The skin of the affected area is smooth while the subject is standing or lying down, but the alterations in the surface of the skin can be seen when the skin is pinched or there is a muscle contraction; ☞ Type III: There is an orange skin appearance when standing, without the use of any device to observe it; ☞ Type IV: There is an orange skin appearance when standing, without the use of any device to observe it, in addition to the presence of raised areas and nodules. <p>☞ Cosmetic qualities and efficacy: by a questionnaire prepared in collaboration with the Study Monitor, to be filled in by the subject, at home, before the last visit to Labex, and completed with the global appraisal in the presence of the Investigator on D29.</p> |
| <u>DATA ANALISYS</u> | <p><u>Interpretation of the results obtained under the adopted experimental conditions of use, based on:</u></p> <ul style="list-style-type: none"> . the expected effects, according to the Study Monitor, . the type of investigational product, . analysis of the nature, location, intensity, frequency, duration and appearance period of the reactions. <p><u>Clinical scoring and centimeter measurements:</u></p> <ul style="list-style-type: none"> . The average values and the standard deviations of the parameters obtained at each time of the study are calculated from the individual values collected from all the subjects. . Comparison of the values obtained at D29 in relation to the initial values by means of the Wilcoxon test ("two-tail", significance: $p < 0.05$). |

R E S U L T S A N D C O N C L U S I O N

STUDIED POPULATION

| | |
|---|-------------------|
| Number of subjects recruited | 35 |
| Number of subjects who came to Labex. | 23 |
| Number of subjects included by the Investigator | 23 |
| Number of subjects discontinued from the study | 3 |
| - Not linked to an undesirable effect | 0 |
| - Not linked to a serious undesirable effect | 0 |
| - Linked to an undesirable effect | 0 |
| - Linked to a serious undesirable effect | 0 |
| - Concomitant treatment incompatible with the study | 0 |
| - Consent withdrawal by the subject | 0 |
| - Lost to follow up | 3 (n° 01, 05, 15) |
| - Emergence of a non-inclusion criterion | 0 |
| - Decision of the Investigator | 0 |
| - Violation of the protocol | 0 |
| Number of subjects for the analysis of the results | 20 |

The characteristics of the subjects included into the study are summarized in the following table:

| Subjects | Body skin nature | Sensitive body skin |
|-----------------------|-------------------|---------------------|
| Number : 20 | Normal : 9 (45%) | 4 (20%) |
| Women : 20 (100%) | Dry : 10 (50%) | |
| Mean age : 44.5 y.o. | Very dry : 1 (5%) | |
| Age minimum : 29 y.o. | | |
| Age maximum : 57 y.o. | | |
| BMI : 24-32 | | |

| Subjects with cellulite | Subjects with atopy background | Regular users of this kind of product |
|-------------------------|--------------------------------|---------------------------------------|
| 20 (100%) | 2 (10%) | 13 (65%) |

RESULTS AND DISCUSSION

1/ CUTANEOUS ACCEPTABILITY

Analysis of the results obtained revealed, on the whole:

- As regards irritation or discomfort, a very good acceptability of the investigational product in all subjects who took part in the whole study.

It should be noted that no abnormal clinical sign was observed by the Investigator, after 4 weeks of application.

No subject indicated to have had or observed, during the study, any cutaneous reaction of irritation or discomfort.

2/ REDUCING EFFECT

The analysis of the results obtained after the measures of the “abdominal perimeter”, “hips perimeter” and “thigh perimeter” by the technician is detailed below.

The normality of the distribution and the homogeneity of the variances have been verified for all the cases.

After 7 days of use of the investigational product (n = 20):

ABDOMINAL

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|---------------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D8 | Δ (D8 - D1) | Probability p: Wilcoxon Test |
| Abdominal perimeter (cm) | 96.55 ± 1.85 | 93.60 ± 1.68 | -2.95 ± 0.59 | < 0.0001 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “abdominal perimeter” parameter, after 7 days of use of the investigational product, in comparison with the initial values. This means that the abdominal perimeter has been significantly reduced after 7 days of use.

HIPS

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|----------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D8 | Δ (D8 - D1) | Probability p: Wilcoxon Test |
| Hips perimeter (cm) | 88.00 ± 1.72 | 86.70 ± 1.64 | -1.30 ± 0.27 | 0.0002 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “hips perimeter” parameter, after 7 days of use of the investigational product, in comparison with the initial values. This means that the hips perimeter has been significantly reduced after 7 days of use.

THIGH

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|-----------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D8 | Δ (D8 - D1) | Probability p: Wilcoxon Test |
| Thigh perimeter (cm) | 61.80 ± 0.88 | 61.00 ± 0.85 | -0.80 ± 0.17 | 0.0005 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “thigh perimeter” parameter, after 7 days of use of the investigational product, in comparison with the initial values. This means that the thigh perimeter has been significantly reduced after 7 days of use.

After 4 weeks of use of the investigational product (n = 20):

ABDOMINAL

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|---------------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D29 | Δ (D29 - D1) | Probability p: Wilcoxon Test |
| Abdominal perimeter (cm) | 96.55 ± 1.85 | 93.15 ± 1.58 | -3.40 ± 1.03 | 0.0046 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “abdominal perimeter” parameter, after 4 weeks of use of the investigational product, in comparison with the initial values. This means that the abdominal perimeter has been significantly reduced after 4 weeks of use.

HIPS

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|----------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D29 | Δ (D29 - D1) | Probability p: Wilcoxon Test |
| Hips perimeter (cm) | 88.00 ± 1.72 | 86.00 ± 1.56 | -2.00 ± 0.60 | 0.0020 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “hips perimeter” parameter, after 4 weeks of use of the investigational product, in comparison with the initial values. This means that the hips perimeter has been significantly reduced after 4 weeks of use.

THIGH

| | Mean and standard error of the mean – S.E.M (n = 20) | | | |
|-----------------------------|--|--------------|--------------|---------------------------------|
| | D1 | D29 | Δ (D29 - D1) | Probability p: Wilcoxon Test |
| Thigh perimeter (cm) | 61.80 ± 0.88 | 60.10 ± 0.81 | -1.7 ± 0.29 | < 0.0001 |

In bold: Statistically significant probability (significance: $p < 0.05$)

It has been found differences statistically significant for the “thigh perimeter” parameter, after 4 weeks of use of the investigational product, in comparison with the initial values. This means that the thigh perimeter has been significantly reduced after 4 weeks of use.

3/ CELLULITE IMPROVEMENT

- In reference to the scoring of the "cellulite improvement" parameter: visual scale of 4 points (from 0 to 3) Nürnberger-Müller.

After 7 days of use of the investigational product:

EVALUATION BY THE SUBJECTS (n=20)

| | n | Mean and standard error of the mean (S.E.M.) | | Variation percentage # | Probability p: Wilcoxon Test |
|------------------------------|-----------|---|-------------|---------------------------|---------------------------------|
| | | D1 Initial value | D8 | | |
| Cellulite improvement | 20 | 1.55 ± 0.15 | 1.50 ± 0.14 | 2% | >0.9999 |

*italics: probability not statistically significant: $p > 0.10$
variation compared to the initial values*

It has been not found differences statistically significant in the "cellulite improvement" parameter, after 7 days of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product not provides a cellulite improvement after 7 days of application.

EVALUATION BY THE INVESTIGATOR (n=20)

| | n | Mean and standard error of the mean (S.E.M.) | | Variation percentage # | Probability p: Wilcoxon Test |
|------------------------------|-----------|---|-------------|---------------------------|---------------------------------|
| | | D1 Initial value | D8 | | |
| Cellulite improvement | 20 | 1.70 ± 0.16 | 1.70 ± 0.16 | 0% | >0.9999 |

*italics: probability not statistically significant: $p > 0.10$
variation compared to the initial values*

It has been not found differences statistically significant in the "cellulite improvement" parameter, after 7 days of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product not provides a cellulite improvement after 7 days of application.

- In reference to the scoring of the "cellulite improvement" parameter: visual scale of 4 points (from 0 to 3) Nürnberger-Müller.

After 4 weeks of use of the investigational product:

EVALUATION BY THE SUBJECTS (n=20)

| | n | Mean and standard error of the mean (S.E.M.) | | Variation percentage # | Probability p: Wilcoxon Test |
|------------------------------|-----------|---|--------------------|---------------------------|---------------------------------|
| | | D1 Initial value | D29 Final value | | |
| Cellulite improvement | 20 | 1.55 ± 0.15 | 1.20 ± 0.16 | 24% | <0.0001 |

Bold: Probability statistically significant: $p < 0.05$
variation compared to the initial values

It has been found differences statistically significant in the "cellulite improvement" parameter, after 4 weeks of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product provides a cellulite improvement after 4 weeks of application.

EVALUATION BY THE INVESTIGATOR (n=20)

| | n | Mean and standard error of the mean (S.E.M.) | | Variation percentage # | Probability p: Wilcoxon Test |
|------------------------------|-----------|---|--------------------|---------------------------|---------------------------------|
| | | D1 Initial value | D29 Final value | | |
| Cellulite improvement | 20 | 1.70 ± 0.16 | 1.35 ± 0.17 | 21% | 0.0156 |

Bold: Probability statistically significant: $p < 0.05$
variation compared to the initial values

It has been found differences statistically significant in the "cellulite improvement" parameter, after 4 weeks of use of the investigational product, in comparison with the initial values. This means that the application of the cosmetic investigational product provides a cellulite improvement after 4 weeks of application.

4/ COSMETIC ACCEPTABILITY AND EFFICACY

As regards its efficacy, a positive judgment and a favorable appraisal of these subjects for, in particular, the following criteria (in % of the subjects questioned):

| | | |
|--|------|----------|
| The cream is pleasant | 100% | |
| The cream is suitable for your skin type | 100% | |
| The smell of the cream is pleasant | 90% | |
| The texture of the cream is pleasant | 100% | |
| The cream spreads well on the skin | 100% | |
| The cream is quickly absorbed | 95% | |
| The cream provides a comfortable feeling on the skin after application | 100% | |
| The cream leaves the skin hydrated | 100% | |
| The cream respects the natural balance of the skin | 100% | |
| The use of the cream together with the trousers improves the appearance of the skin | 100% | |
| After using the cream together with the trousers, the skin is firmer | 85% | |
| After using the cream together with the trousers, the skin is more elastic | 80% | |
| After using the cream together with the trousers, the skin appears more redensified (consistent, firm and compact) | 80% | |
| After using the cream together with the trousers, the quality of the skin has improved | 75% | |
| After using the cream together with the pants, I notice that I have less cellulite | 85% | |
| The use of the cream together with the trousers is essential for daily use | 80% | |
| Globally, I like the product | 85% | |
| By comparing with the product generally used, the subject found her skin "just as good" to "better" | 100% | (13/13●) |
| Preferred product: | | |
| . investigational product | 77% | (10/13●) |
| . no preference | 23% | (3/13●) |
| . usual product | 0% | (0/13●) |
| By comparing the efficacy of the investigational product with the one normally used: | | |
| . the investigational product was more effective | 69% | (9/13●) |
| . no difference | 31% | (4/13●) |
| . usual product was more effective | 0% | (0/13●) |
| At the end of this study, would buy the cream along with the pants at 49.99€ | 75% | |

● regular users of this kind of product

**The CUTANEOUS ACCEPTABILITY of the investigational product designated as
"VELFORM CELLU WRAP (ref: LOGIC: VCSVFFSET0254)"**

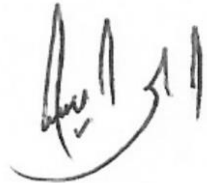
can be judged, on the whole, as VERY GOOD, after repeated use, under normal conditions of use, in the abdomen, thighs and hips, applying the product twice a day and wearing the pant all night long, and following a diet delivered by the Sponsor, for 4 consecutive weeks, by 20 adult female subjects, with a BMI between 24 and 32 and with cellulite.

In the evaluation of the reducing effect: Statistically significant differences were observed for the parameters "reduction of the abdominal perimeter", "reduction of the hips perimeter" and "reduction of the thighs perimeter", after 7 days and after 4 weeks of use of the investigational product, in comparison with the initial values.

In the evaluation of the cellulite improvement: Statistically significant differences were observed after 4 weeks of use of the investigational product in comparison with the initial values.

The claims such as "REDUCING EFFECT" and "CELLULITE IMPROVEMENT" can thus be justified.

Barcelona, 17 January 2020



B. RAIS
Technical Manager

This study was conducted by LABORATOIRE D'EXPERTISE CLINIQUE ESPAGNE, managed by Mr. B. RAÏS, PhD Biological and Medical Sciences, European Registered Toxicologist - EUROTOX.

PROTOCOL COMPLIANCE

2 subjects (10% of the panel) used the investigational product at D29 (day of the clinical examination by the Investigator).

This deviation has not affected in a notable way the quality or the interpretation of the obtained results.

STORAGE OF THE INVESTIGATIONAL PRODUCT

The investigational product was kept under lock and key, from heat (between + 5°C and + 25°C) and from light. A sample of the investigational product will be kept in our facilities for 4 months as of the date of dispatch of the final report. From this date on, and without contrary advice of the Sponsor, the investigational product will be destroyed.

DATA RECORDING AND ARCHIVING

Raw data are defined as all the hand-written information input in the case report form constituted, before the start of the study. Raw data are then synthesized in compilation document, which are mainly electronic Excel o Word files (Microsoft Corp.) or in the questionnaire portal database allow either direct analysis of the data, or transfer to a more specific software for statistical analysis (SPSS ...).

All raw data (case report forms, questionnaires if any), as well as the original documents of the compilation, of the final protocol (amendments if any), of the final report (all different versions and/or amendments if any) and of the statistical analysis if any, are kept in the archives for 10 years at the following addresses:

- . For the 2 to 12 months following dispatch of report:
Labex. S.A.U. Passeig Sant Joan, 76, 08009 Barcelona. Spain.
- . For the following years: in the premises of the company IRON MOUNTAIN,
Head Quarter: PI Rosanes. Av. Republica Federal Alemana. 55-57. Castellvi de Rosanes, 08769 Barcelona.
Spain.

Once this period is over, the Sponsor will be contacted regarding its archives. No archive destruction will be done without the written agreement from the Sponsor.

APPENDICES

TABLE I: BMI MEASUREMENTS D1
(mean and standard error of the mean – S.E.M.)

| VOL. | WEIGHT (kg) | HEIGHT (m) | BMI (D1) |
|-------------|--------------|-------------|--------------|
| 2 | 80.6 | 1.6 | 31.48 |
| 3 | 84.9 | 1.65 | 31.18 |
| 4 | 76.4 | 1.65 | 28.06 |
| 6 | 70.3 | 1.52 | 30.43 |
| 7 | 66.4 | 1.6 | 25.94 |
| 8 | 65.1 | 1.63 | 24.50 |
| 9 | 63.2 | 1.53 | 27.00 |
| 10 | 59.6 | 1.54 | 25.13 |
| 11 | 67.9 | 1.62 | 25.87 |
| 12 | 71.4 | 1.6 | 27.89 |
| 13 | 67.4 | 1.61 | 26.00 |
| 14 | 70.6 | 1.52 | 30.56 |
| 16 | 73.2 | 1.63 | 27.55 |
| 17 | 64.0 | 1.54 | 26.99 |
| 18 | 64.1 | 1.57 | 26.01 |
| 19 | 82.2 | 1.68 | 29.12 |
| 20 | 75.0 | 1.57 | 30.43 |
| 21 | 78.9 | 1.58 | 31.61 |
| 22 | 57.9 | 1.51 | 25.39 |
| 23 | 64.0 | 1.58 | 25.64 |
| MEAN | 70.16 | 1.59 | 27.84 |
| SEM | 1.70 | 0.01 | 0.53 |

TABLE II: BMI MEASUREMENTS D8
(mean and standard error of the mean – S.E.M.)

| VOL. | WEIGHT (kg) | HEIGHT (m) | BMI (D8) |
|-------------|--------------------|-------------------|-----------------|
| 2 | 80.0 | 1.6 | 31.25 |
| 3 | 82.7 | 1.65 | 30.38 |
| 4 | 75.2 | 1.65 | 27.62 |
| 6 | 70.3 | 1.52 | 30.43 |
| 7 | 64.9 | 1.6 | 25.35 |
| 8 | 64.5 | 1.63 | 24.28 |
| 9 | 62.1 | 1.53 | 26.53 |
| 10 | 59.9 | 1.54 | 25.26 |
| 11 | 67.3 | 1.62 | 25.64 |
| 12 | 73.1 | 1.6 | 28.55 |
| 13 | 67.7 | 1.61 | 26.12 |
| 14 | 70.1 | 1.52 | 30.34 |
| 16 | 73.5 | 1.63 | 27.66 |
| 17 | 63.2 | 1.54 | 26.65 |
| 18 | 62.4 | 1.57 | 25.32 |
| 19 | 81.2 | 1.68 | 28.77 |
| 20 | 73.7 | 1.57 | 30.43 |
| 21 | 76.6 | 1.58 | 30.68 |
| 22 | 58.4 | 1.51 | 25.61 |
| 23 | 63.4 | 1.58 | 25.40 |
| MEAN | 69.51 | 1.59 | 27.61 |
| SEM | 1.63 | 0.01 | 0.51 |

TABLE III: BMI MEASUREMENTS D29
(mean and standard error of the mean – S.E.M.)

| VOL. | WEIGHT (kg) | HEIGHT (m) | BMI (D29) |
|-------------|--------------------|-------------------|------------------|
| 2 | 80.0 | 1.6 | 31.25 |
| 3 | 79.1 | 1.65 | 29.05 |
| 4 | 73.7 | 1.65 | 27.07 |
| 6 | 71.0 | 1.52 | 30.73 |
| 7 | 63.7 | 1.6 | 24.88 |
| 8 | 62.4 | 1.63 | 23.49 |
| 9 | 62.8 | 1.53 | 26.83 |
| 10 | 59.1 | 1.54 | 24.92 |
| 11 | 67.7 | 1.62 | 25.80 |
| 12 | 73.3 | 1.6 | 28.63 |
| 13 | 67.7 | 1.61 | 26.12 |
| 14 | 69.4 | 1.52 | 30.04 |
| 16 | 72.7 | 1.63 | 27.36 |
| 17 | 61.8 | 1.54 | 26.06 |
| 18 | 61.0 | 1.57 | 24.75 |
| 19 | 80.5 | 1.68 | 28.52 |
| 20 | 72.3 | 1.57 | 29.33 |
| 21 | 76.6 | 1.58 | 30.68 |
| 22 | 58.0 | 1.51 | 25.44 |
| 23 | 64.1 | 1.58 | 25.68 |
| MEAN | 68.85 | 1.59 | 27.33 |
| SEM | 1.58 | 0.01 | 0.52 |

TABLE IV: WEIGHT MEASUREMENTS D1, D8, D29
(mean and standard error of the mean – S.E.M.)

| VOL. | D1 | D8 | D29 | D8-D1 | D29-D1 |
|-------------|-------|-------|-------|-------|--------|
| 2 | 80.6 | 80.0 | 80.0 | -0.6 | -0.6 |
| 3 | 84.9 | 82.7 | 79.1 | -2.2 | -5.8 |
| 4 | 76.4 | 75.2 | 73.7 | -1.2 | -2.7 |
| 6 | 70.3 | 70.3 | 71.0 | 0.0 | 0.7 |
| 7 | 66.4 | 64.9 | 63.7 | -1.5 | -2.7 |
| 8 | 65.1 | 64.5 | 62.4 | -0.6 | -2.7 |
| 9 | 63.2 | 62.1 | 62.8 | -1.1 | -0.4 |
| 10 | 59.6 | 59.9 | 59.1 | 0.3 | -0.5 |
| 11 | 67.9 | 67.3 | 67.7 | -0.6 | -0.2 |
| 12 | 71.4 | 73.1 | 73.3 | 1.7 | 1.9 |
| 13 | 67.4 | 67.7 | 67.7 | 0.3 | 0.3 |
| 14 | 70.6 | 70.1 | 69.4 | -0.5 | -1.2 |
| 16 | 73.2 | 73.5 | 72.7 | 0.3 | -0.5 |
| 17 | 64.0 | 63.2 | 61.8 | -0.8 | -2.2 |
| 18 | 64.1 | 62.4 | 61.0 | -1.7 | -3.1 |
| 19 | 82.2 | 81.2 | 80.5 | -1.0 | -1.7 |
| 20 | 75.0 | 73.7 | 72.3 | -1.3 | -2.7 |
| 21 | 78.9 | 76.6 | 76.6 | -2.3 | -2.3 |
| 22 | 57.9 | 58.4 | 58.0 | 0.5 | 0.1 |
| 23 | 64.0 | 63.4 | 64.1 | -0.6 | 0.1 |
| MEAN | 70.16 | 69.51 | 68.85 | -0.65 | -1.31 |
| SEM | 1.70 | 1.63 | 1.58 | 0.22 | 0.39 |

TABLE V: ABDOMINAL MEASUREMENTS D1, D8, D29
(mean and standard error of the mean – S.E.M.)

| VOL. | D1 | D8 | D29 | D8-D1 | D29-D1 |
|-------------|--------------|--------------|--------------|--------------|---------------|
| 2 | 105.0 | 101.0 | 101.0 | -4.0 | -4.0 |
| 3 | 116.0 | 110.0 | 108.0 | -6.0 | -8.0 |
| 4 | 99.0 | 92.0 | 90.0 | -7.0 | -9.0 |
| 6 | 103.0 | 100.0 | 100.0 | -3.0 | -3.0 |
| 7 | 96.0 | 91.0 | 88.0 | -5.0 | -8.0 |
| 8 | 96.0 | 94.0 | 92.0 | -2.0 | -4.0 |
| 9 | 97.0 | 95.0 | 99.0 | -2.0 | 2.0 |
| 10 | 83.0 | 80.0 | 80.0 | -3.0 | -3.0 |
| 11 | 82.0 | 81.0 | 90.0 | -1.0 | 8.0 |
| 12 | 97.0 | 95.0 | 95.0 | -2.0 | -2.0 |
| 13 | 90.0 | 90.0 | 94.0 | 0.0 | 4.0 |
| 14 | 100.0 | 99.0 | 96.0 | -1.0 | -4.0 |
| 16 | 100.0 | 99.0 | 97.0 | -1.0 | -3.0 |
| 17 | 96.0 | 95.0 | 92.0 | -1.0 | -4.0 |
| 18 | 95.0 | 85.0 | 83.0 | -10.0 | -12.0 |
| 19 | 92.0 | 88.0 | 87.0 | -4.0 | -5.0 |
| 20 | 98.0 | 96.0 | 91.0 | -2.0 | -7.0 |
| 21 | 109.0 | 104.0 | 104.0 | -5.0 | -5.0 |
| 22 | 85.0 | 86.0 | 85.0 | 1.0 | 0.0 |
| 23 | 92.0 | 91.0 | 91.0 | -1.0 | -1.0 |
| MEAN | 96.55 | 93.60 | 93.15 | -2.95 | -3.40 |
| SEM | 1.85 | 1.68 | 1.58 | 0.59 | 1.03 |

TABLE VI: THIGHS MEASUREMENTS D1, D8, D29
(mean and standard error of the mean – S.E.M.)

| VOL. | D1 | D8 | D29 | D8-D1 | D29-D1 |
|-------------|--------------|--------------|--------------|--------------|---------------|
| 2 | 66.0 | 66.0 | 65.0 | 0.0 | -1.0 |
| 3 | 62.0 | 61.0 | 59.0 | -1.0 | -3.0 |
| 4 | 69.0 | 67.0 | 66.0 | -2.0 | -3.0 |
| 6 | 58.0 | 57.0 | 57.0 | -1.0 | -1.0 |
| 7 | 57.0 | 56.0 | 55.0 | -1.0 | -2.0 |
| 8 | 57.0 | 57.0 | 57.0 | 0.0 | 0.0 |
| 9 | 57.0 | 56.0 | 56.0 | -1.0 | -1.0 |
| 10 | 56.0 | 56.0 | 55.0 | 0.0 | -1.0 |
| 11 | 62.0 | 61.0 | 61.0 | -1.0 | -1.0 |
| 12 | 61.0 | 61.0 | 62.0 | 0.0 | 1.0 |
| 13 | 63.0 | 62.0 | 59.0 | -1.0 | -4.0 |
| 14 | 63.0 | 61.0 | 61.0 | -2.0 | -2.0 |
| 16 | 63.0 | 63.0 | 61.0 | 0.0 | -2.0 |
| 17 | 59.0 | 59.0 | 57.0 | 0.0 | -2.0 |
| 18 | 61.0 | 59.0 | 57.0 | -2.0 | -4.0 |
| 19 | 70.0 | 69.0 | 67.0 | -1.0 | -3.0 |
| 20 | 65.0 | 64.0 | 63.0 | -1.0 | -2.0 |
| 21 | 65.0 | 65.0 | 64.0 | 0.0 | -1.0 |
| 22 | 63.0 | 61.0 | 61.0 | -2.0 | -2.0 |
| 23 | 59.0 | 59.0 | 59.0 | 0.0 | 0.0 |
| MEAN | 61.80 | 61.00 | 60.10 | -0.80 | -1.70 |
| SEM | 0.88 | 0.85 | 0.81 | 0.17 | 0.29 |

TABLE VII: HIPS MEASUREMENTS D1, D8, D29
(mean and standard error of the mean – S.E.M.)

| VOL. | D1 | D8 | D29 | D8-D1 | D29-D1 |
|-------------|-----------|-----------|------------|--------------|---------------|
| 2 | 100.0 | 97.0 | 97.0 | -3.0 | -3.0 |
| 3 | 106.0 | 104.0 | 99.0 | -2.0 | -7.0 |
| 4 | 83.0 | 81.0 | 79.0 | -2.0 | -4.0 |
| 6 | 99.0 | 97.0 | 97.0 | -2.0 | -2.0 |
| 7 | 86.0 | 83.0 | 83.0 | -3.0 | -3.0 |
| 8 | 88.0 | 86.0 | 84.0 | -2.0 | -4.0 |
| 9 | 88.0 | 88.0 | 90.0 | 0.0 | 2.0 |
| 10 | 79.0 | 79.0 | 79.0 | 0.0 | 0.0 |
| 11 | 81.0 | 80.0 | 79.0 | -1.0 | -2.0 |
| 12 | 84.0 | 84.0 | 85.0 | 0.0 | 1.0 |
| 13 | 80.0 | 79.0 | 82.0 | -1.0 | 2.0 |
| 14 | 92.0 | 92.0 | 90.0 | 0.0 | -2.0 |
| 16 | 92.0 | 92.0 | 92.0 | 0.0 | 0.0 |
| 17 | 90.0 | 86.0 | 82.0 | -4.0 | -8.0 |
| 18 | 83.0 | 82.0 | 79.0 | -1.0 | -4.0 |
| 19 | 85.0 | 83.0 | 82.0 | -2.0 | -3.0 |
| 20 | 88.0 | 88.0 | 86.0 | 0.0 | -2.0 |
| 21 | 94.0 | 93.0 | 94.0 | -1.0 | 0.0 |
| 22 | 74.0 | 74.0 | 75.0 | 0.0 | 1.0 |
| 23 | 88.0 | 86.0 | 86.0 | -2.0 | -2.0 |
| MEAN | 88.00 | 86.70 | 86.00 | -1.30 | -2.00 |
| SEM | 1.72 | 1.64 | 1.56 | 0.27 | 0.60 |