



Clinical trial results:

Treatment of striae distensae with fractional radiofrequency and topical tretinoin: An intra-individual study with blinded outcome assessment

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2021-003153-39 |
| Trial protocol | DK |
| Global end of trial date | 05 July 2023 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 21 July 2024 |
| First version publication date | 21 July 2024 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | SDRFTT |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05461755 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Bispebjerg Hospital |
| Sponsor organisation address | Nielsine Nielsens Vej 17, Copenhagen NV, Denmark, 2400 |
| Public contact | Merete Haedersdal, Bispebjerg Hospital, Department of Dermatology, 0045 24454393, merete.haedersdal@regionh.dk |
| Scientific contact | Gabriela Lladó Grove, Bispebjerg Hospital, Department of Dermatology, 0045 24454393, ggro0013@regionh.dk |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 05 July 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 05 July 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 July 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The study aims to explore the potential of combination therapy with fractional radiofrequency and topical tretinoin for treatment and overall improvement of striae albae.

Protection of trial subjects:

Safe, established interventions. Monthly clinical visits the first two months and a final visit at 20-weeks. Open contact to the treating clinician in case of questions during the entire trial.

Background therapy:

No other therapies than the interventional treatments

Evidence for comparator:

In the background literature in the field both fractional energy-based devices (such as radiofrequency) and topical tretinoin have been associated with skin remodeling for improvement of e.g. scars including striae

| | |
|---|-------------------------------|
| Actual start date of recruitment | 22 November 2022 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Scientific research |
| Long term follow-up duration | 3 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Denmark: 20 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 20 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |

| | |
|----------------------|----|
| Adults (18-64 years) | 20 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Recruitment was conducted in the clinical setting at Dept of Dermatology, Copenhagen University Hospital (Bispebjerg) including patients between 22.11.22 - 08.03.23

Pre-assignment

Screening details:

According to pre-defined inclusion and exclusion criteria

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

N/A

Arms

| | |
|------------------------------|------------------|
| Are arms mutually exclusive? | No |
| Arm title | FRF+TT treatment |

Arm description:

Fractional Radiofrequency and Topical tretinoin

| | |
|--|----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Tretinoin |
| Investigational medicinal product code | |
| Other name | Retirides 0.1% |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical |

Dosage and administration details:

tubes of 30 g, 1mg/g, topical application according to protocol

| | |
|------------------|--------------|
| Arm title | TT treatment |
|------------------|--------------|

Arm description:

Topical tretinoin

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Tretinoin |
| Investigational medicinal product code | |
| Other name | Retirides 0.1% |
| Pharmaceutical forms | Cream |
| Routes of administration | Topical |

Dosage and administration details:

tubes of 30 g, 1mg/g, topical application according to protocol

| | |
|------------------|---------------|
| Arm title | FRF treatment |
|------------------|---------------|

Arm description:

Fractional radiofrequency

| | |
|---|----------------|
| Arm type | Medical device |
| No investigational medicinal product assigned in this arm | |

| | |
|------------------|---------|
| Arm title | Control |
|------------------|---------|

Arm description:

Untreated control

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 1 | FRF+TT treatment | TT treatment | FRF treatment |
|---------------------------------------|------------------|--------------|---------------|
| Started | 20 | 20 | 20 |
| Completed | 19 | 19 | 19 |
| Not completed | 1 | 1 | 1 |
| Lost to follow-up | 1 | 1 | 1 |

| Number of subjects in period 1 | Control |
|---------------------------------------|---------|
| Started | 20 |
| Completed | 19 |
| Not completed | 1 |
| Lost to follow-up | 1 |

Baseline characteristics

Reporting groups

| | |
|--|---------------|
| Reporting group title | Overall trial |
| Reporting group description: | |
| 20 patients at baseline, each receiving treatment with FRF+TT, TT, FRF and untreated control in four comparable areas (by randomization) | |

| Reporting group values | Overall trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 20 | 20 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | | 0 | |
| Newborns (0-27 days) | | 0 | |
| Infants and toddlers (28 days-23 months) | | 0 | |
| Children (2-11 years) | | 0 | |
| Adolescents (12-17 years) | | 0 | |
| Adults (18-64 years) | | 0 | |
| From 65-84 years | | 0 | |
| 85 years and over | | 0 | |
| Age continuous | | | |
| Age at baseline | | | |
| Units: years | | | |
| median | 31 | | |
| inter-quartile range (Q1-Q3) | 28 to 37 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 19 | 19 | |
| Male | 1 | 1 | |
| Previous striae treatment | | | |
| previous interventional striae treatment | | | |
| Units: Subjects | | | |
| Yes | 1 | 1 | |
| No | 19 | 19 | |
| Body mass index | | | |
| BMI | | | |
| Units: kilogram(s)/square metre | | | |
| median | 24.0 | | |
| inter-quartile range (Q1-Q3) | 21.2 to 26.4 | - | |
| TT study usage | | | |
| Topical tretinoin study usage | | | |
| Units: gram(s) | | | |
| median | 17.2 | | |
| inter-quartile range (Q1-Q3) | 13.5 to 22.9 | - | |
| Treatment areas size | | | |
| Size of treatment areas | | | |
| Units: square centimetre | | | |

| | | | |
|------------------------------|----------|---|--|
| median | 46.5 | | |
| inter-quartile range (Q1-Q3) | 32 to 62 | - | |

End points

End points reporting groups

| | |
|---|------------------|
| Reporting group title | FRF+TT treatment |
| Reporting group description: Fractional Radiofrequency and Topical tretinoin | |
| Reporting group title | TT treatment |
| Reporting group description: Topical tretinoin | |
| Reporting group title | FRF treatment |
| Reporting group description: Fractional radiofrequency | |
| Reporting group title | Control |
| Reporting group description: Untreated control | |

Primary: POSAS-PT SUM

| | |
|---|--------------|
| End point title | POSAS-PT SUM |
| End point description: | |
| End point type | Primary |
| End point timeframe: Baseline compared to 20-week follow-up on patient POSAS sum | |

| End point values | FRF+TT treatment | TT treatment | FRF treatment | Control |
|---------------------------------------|------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 19 | 19 | 19 | 19 |
| Units: point | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| Baseline | 25 (19 to 31) | 25 (20 to 33) | 24 (20 to 33) | 24 (20 to 30) |
| Follow-up | 15 (10 to 22) | 19 (12 to 25) | 17 (13 to 24) | 19 (14 to 25) |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Delta baseline vs follow-up |
| Statistical analysis description: Baseline vs follow-up for each area | |
| Comparison groups | FRF+TT treatment v TT treatment v FRF treatment v Control |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 76 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence ^[1] |
| P-value | < 0.05 ^[2] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[1] - Baseline compared to 20-week follow-up

[2] - Delta only significantly different between FRF+TT and control in favor of FRF+TT

Secondary: POSAS-PT OVERALL

| | |
|-----------------|------------------|
| End point title | POSAS-PT OVERALL |
|-----------------|------------------|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline compared to 20-week follow-up on patient POSAS overall

| End point values | FRF+TT treatment | TT treatment | FRF treatment | Control |
|---------------------------------------|------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 19 | 19 | 19 | 19 |
| Units: point | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| Baseline | 7 (4 to 9) | 7 (5 to 8) | 7 (4 to 9) | 7 (5 to 8) |
| Follow-up | 4 (3 to 6) | 5 (3 to 7) | 4 (3 to 6) | 5 (4 to 7) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Delta baseline vs follow-up |
| Comparison groups | FRF+TT treatment v TT treatment v FRF treatment v Control |
| Number of subjects included in analysis | 76 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | < 0.005 ^[3] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[3] - Delta only significantly different between FRF+TT and control in favor of FRF+TT

Secondary: POSAS-OBS SUM

| | |
|-----------------|---------------|
| End point title | POSAS-OBS SUM |
|-----------------|---------------|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline compared to 20-week follow-up on Observer POSAS sum

| End point values | FRF+TT treatment | TT treatment | FRF treatment | Control |
|---------------------------------------|------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 19 | 19 | 19 | 19 |
| Units: point | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| Baseline | 12 (8 to 15) | 12 (9 to 14) | 12 (9 to 15) | 12 (8 to 14) |
| Follow-up | 10 (9 to 14) | 11 (10 to 12) | 12 (10 to 15) | 11 (10 to 12) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Delta baseline vs follow-up |
| Comparison groups | FRF+TT treatment v TT treatment v FRF treatment v Control |
| Number of subjects included in analysis | 76 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | > 0.05 ^[4] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[4] - Delta non significant in all areas

Secondary: POSAS-OBS OVERALL

| | |
|--|-------------------|
| End point title | POSAS-OBS OVERALL |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline compared to 20-week follow-up on observer POSAS overall | |

| End point values | FRF+TT treatment | TT treatment | FRF treatment | Control |
|---------------------------------------|------------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 19 | 19 | 19 | 19 |
| Units: point | | | | |
| median (inter-quartile range (Q1-Q3)) | | | | |
| Baseline | 3 (2 to 4) | 3 (2 to 4) | 3 (2 to 4) | 3 (2 to 4) |
| Follow-up | 2 (2 to 3) | 3 (2 to 3) | 2 (2 to 3) | 2 (2 to 3) |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Delta baseline vs follow-up |
| Comparison groups | FRF+TT treatment v TT treatment v FRF treatment v Control |
| Number of subjects included in analysis | 76 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | < 0.05 ^[5] |
| Method | Wilcoxon (Mann-Whitney) |

Notes:

[5] - Except for TT delta p=0.148. No statistical difference of deltas between arms

Secondary: Safety - procedural pain

| | |
|---|---|
| End point title | Safety - procedural pain ^[6] |
| End point description: | |
| Procedural pain from isolated FRF by anatomic site on a numerical rating scale (0-10) | |
| End point type | Secondary |
| End point timeframe: | |
| First treatment session | |

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Procedural pain only relevant for the isolated procedural treatment with FRF

| | | | | |
|-------------------------------|-----------------|--|--|--|
| End point values | FRF treatment | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 20 | | | |
| Units: score | | | | |
| median (full range (min-max)) | | | | |
| Abdomen | 3 (2 to 7) | | | |
| Nates | 2.5 (2 to 3) | | | |
| Inner thighs | 4 (4 to 8) | | | |
| Hips | 4 (4 to 4) | | | |
| Lower back | 5 (5 to 5) | | | |
| Knees | 6 (6 to 6) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Baseline until 20-week follow-up

Adverse event reporting additional description:

According to GCP and the Danish Medicines Agency with yearly reports

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|------|
| Dictionary name | None |
|-----------------|------|

| | |
|--------------------|---|
| Dictionary version | 0 |
|--------------------|---|

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious AE/AR above frequency threshold for reporting non-serious adverse events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Quantitative assessment of striae apperance with images not possible due to image quality.

Notes: