



## 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
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##### 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
<b>Arm title</b>	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

<b>Arm title</b>	TT treatment
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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

<b>Arm title</b>	FRF treatment
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Arm description:

Fractional radiofrequency

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

<b>Arm title</b>	Control
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Arm description:

Untreated control

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

<b>Number of subjects in period 1</b>	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

<b>Number of subjects in period 1</b>	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 <sup>[1]</sup>
P-value	< 0.05 <sup>[2]</sup>
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
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End point description:

End point type	Secondary
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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 <sup>[3]</sup>
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
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End point description:

End point type	Secondary
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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 <sup>[4]</sup>
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

<b>Statistical analysis title</b>	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 <sup>[5]</sup>
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 <sup>[6]</sup>
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

<b>End point values</b>	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

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

Baseline until 20-week follow-up

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Adverse event reporting additional description:

According to GCP and the Danish Medicines Agency with yearly reports

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Assessment type
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Systematic
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### Dictionary used

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Dictionary name
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None
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Dictionary version
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0
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Frequency threshold for reporting non-serious adverse events: 5 %

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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

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### 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.
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Notes: