Clinical trial results:
Investigator-initiated clinical research trial on the effects of 5% Minoxidil topical foam on gene expression, hair growth and scalp microenvironment in men with androgenetic alopecia

Summary

EudraCT number	2013-004130-15
Trial protocol	DE
Global end of trial date	29 September 2014

Results information

Result version number	v1 (current)
This version publication date	15 December 2021
First version publication date	15 December 2021
Summary attachment (see zip file)	Final report Synopisis (CRC-AGA-M-A-11 Report Synopsis.pdf)

Trial information

Trial identification

Sponsor protocol code	CRC-AGA-M-A-11

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Charité-Universtitätsmedizin Berlin, Dept. of Dermatology
Sponsor organisation address	Charitéplatz 1, Berlin, Germany, 10117
Public contact	Dr. Kathrin Hillmann, Charité-Universitätsmedizin Berlin, Dept. of Dermatology, Clinical Research Center Hair Skin Science, 0049 030450518499, kathrin.hillmann@charite.de
Scientific contact	Dr. Kathrin Hillmann, Charité-Universitätsmedizin Berlin, Dept. of Dermatology, Clinical Research Center Hair Skin Science, 0049 030450518499, kathrin.hillmann@charite.de

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	02 June 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

-Identifying changes on gene expression level associated with minoxidil treatment with special regard to profiles of genes relevant for AGA treatment and for specific effects of early minoxidil action, respectively (1) minoxidil sulfotransferases, potassium channel regulation (2) inflammation, (3) vasoregulation and (4) sexual hormone production and metabolism;

Protection of trial subjects:

The dosage of the active ingredients of the test product corresponds to 2 x 50 mg minoxidil per day = 100 mg/day.
If, contrary to expectations, a hypersensitivity or allergic reaction should occur, this would lead to the immediate discontinuation of the study participation of the respective volunteer, followed by medical treatment and close medical follow-up.
Each visit is accompanied by a thorough inspection of the scalp by the investigator to ensure safety for the further course of the study.
The subjects must visit the study centre nine times during the course of the 8-week study to document the condition of alopecia by means of the diagnostic tests. These documents are stored in pseudonymised form and used for scientific purposes, again only in anonymised form.
Allergic or hypersensitivity reactions to the hair dye, tattoo ink or disinfectant may occur occasionally (≥1/1000 to 1/100) A spot tattoo on the scalp may cause bleeding, which quickly stops. Inflammation, damage or irritation of nerves is generally rare (≥1/10000 to 1/1000).
In other studies on the use of minoxidil foam, itching, desquamation (2.8%) and inflammation of the skin (1.7%) occurred in 4.4% of cases.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	01 April 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	12
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Monocenter trial in Clinical Research Center for Hair and Skin Science, Dept. of Dermatology, Charité-Universitätsmedizin Berlin:
First patient in 19.05.2014
Last patient out 29.09.2014

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	12
Number of subjects completed	12

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Minoxidil / Vertex

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Minoxidil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use

Dosage and administration details:

Minoxidl 5% foam = 50mg/g
Apllication of 1g of foam twice daily on the balding spot in vertex area

Arm title	No treatment / Occipital

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Minoxidil / Vertex	No treatment / Occipital
Started	12	12
Completed	12	12

Period 2	
Period 2 title	Week 5
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	No
Arm title	Minoxidil / Vertex
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Minoxidil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use
Dosage and administration details: Minoxidl 5% foam = 50mg/g Apllication of 1g of foam twice daily on the balding spot in vertex area	
Arm title	No treatment / Occipital
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Minoxidil / Vertex	No treatment / Occipital
Started	12	12
Completed	12	12

Period 3	
Period 3 title	Week 9
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	No

Arm title	Minoxidil / vertex
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Minoxidil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Topical use
Dosage and administration details: Minoxidl 5% foam = 50mg/g Apllication of 1g of foam twice daily on the balding spot in vertex area	
Arm title	No treatment / occipital
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3	Minoxidil / vertex	No treatment / occipital
Started	12	12
Completed	12	12

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	12	12	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	12	12	

End points

End points reporting groups

Reporting group title	Minoxidil / Vertex
Reporting group description: -	
Reporting group title	No treatment / Occipital
Reporting group description: -	
Reporting group title	Minoxidil / Vertex
Reporting group description: -	
Reporting group title	No treatment / Occipital
Reporting group description: -	
Reporting group title	Minoxidil / vertex
Reporting group description: -	
Reporting group title	No treatment / occipital
Reporting group description: -	

Primary: Phototrichogram: hair density

End point title	Phototrichogram: hair density[1]
End point description:	
End point type	Primary
End point timeframe:	
baseline, week 5, week 9	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis

End point values	Minoxidil / Vertex	No treatment / Occipital	Minoxidil / Vertex	No treatment / Occipital
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: cm²				
arithmetic mean (standard deviation)	192.32 (± 22.04)	206.29 (± 31.35)	194.19 (± 38.90)	201.23 (± 30.34)

End point values	Minoxidil / vertex	No treatment / occipital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: cm²				
arithmetic mean (standard deviation)	211.49 (± 36.98)	217.40 (± 40.21)		

Attachments (see zip file)	Phototrichogram hair density vertex/PTG hair density.jpg

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Sebum level

End point title	Sebum level

End point description:

End point type	Other pre-specified

End point timeframe:

Baseline, Week 5, Week 9

End point values	Minoxidil / Vertex	No treatment / Occipital	Minoxidil / Vertex	No treatment / Occipital
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: µg/cm²				
arithmetic mean (standard deviation)	140.2 (± 95.80)	84.0 (± 93.90)	113.4 (± 125.25)	109.6 (± 114.62)

End point values	Minoxidil / vertex	No treatment / occipital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: µg/cm²				
arithmetic mean (standard deviation)	103.0 (± 94.58)	70.1 (± 79.34)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: pH value

End point title	pH value

End point description:

End point type	Other pre-specified

End point timeframe:

baseline, week 5, week 9

End point values	Minoxidil / Vertex	No treatment / Occipital	Minoxidil / Vertex	No treatment / Occipital
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: none				
arithmetic mean (standard deviation)	5.2 (± 0.93)	5.2 (± 0.59)	5.8 (± 1.18)	5.7 (± 1.24)

End point values	Minoxidil / vertex	No treatment / occipital		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: none				
arithmetic mean (standard deviation)	5.8 (± 1.18)	5.1 (± 0.73)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From baseline to Week 9	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	no dictionary
Dictionary version	0
Reporting groups	
Reporting group title	Related AEs

Reporting group description: -

Serious adverse events	Related AEs		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Related AEs		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)		
Musculoskeletal and connective tissue disorders			
Headache			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Burning skin	Additional description: Burning on application area		
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
skin tingling sensation			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

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

None reported