Clinical trial results:
Efficacy of roflumilast in the treatment of psoriasis – a randomised controlled trial

Summary

EudraCT number	2020-000711-76
Trial protocol	DK
Global end of trial date	25 April 2024

Results information

Result version number	v1 (current)
This version publication date	16 August 2025
First version publication date	16 August 2025

Trial information

Trial identification

Sponsor protocol code	N/A

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Alexander Egeberg, Bispebjerg Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen, Denmark,
Public contact	Bispebjerg Hospital, Alexander Egeberg, alexander.egeberg@gmail.com
Scientific contact	Bispebjerg Hospital, Alexander Egeberg, alexander.egeberg@gmail.com

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	25 April 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 April 2024
Global end of trial reached?	Yes
Global end of trial date	25 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy of roflumilast in the treatment of psoriasis (PASI75)

Protection of trial subjects:

Regulatory approvals were obtained from The Scientific Ethics Committee of the Capital Region of Denmark (H-20013697), the Danish Medicine Agency, and the Danish Data Protection Agency. The trial was registered at EudraCT (2020-000711-76) and conducted in accordance with national data protection acts and the Edinburgh, Scotland, amendment (2000) to the Declaration of Helsinki 1964. Monitoring was performed by the Good Clinical Practice (GCP) units at University of Copenhagen and Aarhus University, Denmark.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 July 2020
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	Denmark: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	23
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from study sites and dermatology private practices, and through advertising.

Pre-assignment

Screening details:

Inclusion criteria were age ≥18 years, chronic stable plaque psoriasis (min. six months duration), psoriasis area and severity index (PASI) ≥8, body mass index (BMI) ≥20 kg/m2, indication for systemic treatment of psoriasis, and safe anticonception during the study period (...) For further details, please see published paper.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

n=18 particiants completed w12. n=5 were failure due to e.g. AEs. There seems to be a technical problem with the software, as the information is not by the system. Please see published paper for more details.

Arm type	Experimental
Investigational medicinal product name	Roflumilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

500 microgram once-daily

Arm title	Placebo

Arm description:

n=22 particiants completed w12. n=1 were failure due to AEs. There seems to be a technical problem with the software, as this information cannot be accepted by the system. Please see published paper for more details.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

Once-daily

Number of subjects in period 1	Active	Placebo
Started	23	23
Completed	23	23

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	46	46	
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)	23	23	
From 65-84 years	23	23	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	12	12	
Male	34	34	

End points

End points reporting groups

Reporting group title	Active

Reporting group description:

n=18 particiants completed w12. n=5 were failure due to e.g. AEs. There seems to be a technical problem with the software, as the information is not by the system. Please see published paper for more details.

Reporting group title	Placebo

Reporting group description:

n=22 particiants completed w12. n=1 were failure due to AEs. There seems to be a technical problem with the software, as this information cannot be accepted by the system. Please see published paper for more details.

Primary: PASI75

End point title	PASI75

End point description:

The primary study endpoint was defined as the proportion of patients achieving at least 75% reduction from baseline PASI (PASI75) at week 12.

End point type	Primary

End point timeframe:

w0-12

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: %	23	23		

Statistical analyses

Statistical analysis title	See below

Statistical analysis description:

Continuous variables were presented as means and standard deviations (SD) (normally distributed data) or medians and interquartile ranges (IQR) (non-normally distributed data). Categorical variables were reported as frequencies and percentages. Efficacy data were assessed by intention to treat (..) For further details, se published paper.

Comparison groups	Active v Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 5
Method	N/A

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: w0-96	
Assessment type	Systematic

Dictionary used	
Dictionary name	N/A
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 0 %

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 SAEs were reported, and no significant biochemical changes were observed.

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