Clinical trial results:
A Multicentre, Open-label, Single-group Maximal Use Trial, Evaluating the Safety and Pharmacokinetic Profile of the Active Ingredients and their Metabolites after application of MC2-01 Cream in Adolescent Subjects (age 12 to 16 years, 11 months) with Extensive Psoriasis Vulgaris

Summary

EudraCT number	2018-000685-12
Trial protocol	DE CZ HU
Global end of trial date	27 May 2020

Results information

Result version number	v1 (current)
This version publication date	21 March 2021
First version publication date	21 March 2021

Trial information

Trial identification

Sponsor protocol code	MC2-01-C6

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03819218
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MC2 Therapeutic Ltd
Sponsor organisation address	C/O Agern Allé 24-26, Hørsholm, Denmark, 2970
Public contact	Senior Project Manager, Clinical Operations, MC2 Therapeutics Ltd, +45 20157033, isa@mc2therapeutics.com
Scientific contact	Senior Project Manager, Clinical Operations, MC2 Therapeutics Ltd, +44 20157033, isa@mc2therapeutics.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	27 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 May 2020
Global end of trial reached?	Yes
Global end of trial date	27 May 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of MC2-01 cream on the HPA axis and calcium metabolism following once daily topical application under maximum-use conditions in subjects with extensive psoriasis vulgaris.

Protection of trial subjects:

The MC2-01 cream contains two well-known active compounds (CAL/BDP) in a novel topical formulation. The efficacy and safety profile of the combination is well established and have proven to be safe and efficacious, and available data for MC2-01 cream suggest a very benign safety profile resembling that known from the approved CAL/BDP products. A cream formulation of CAL and BDP may benefit subjects by providing improved convenience and ease of use resulting in increased patient adherence to therapy which will improve real-life treatment outcome.

It was thus considered that the benefit of obtaining clinical data for this trial outweighed any potential risks.

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and until the final follow-up visit. AEs that were considered related to the trial product would be followed until they were resolved, or until the medical condition of the subject was stable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2018
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	Czechia: 5
Country: Number of subjects enrolled	Germany: 2
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	7
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All subjects approached for the study were either ongoing or new patients referred to the clinics with the diagnosis Psoriasis Vulgaris.

Pre-assignment

Screening details:

Prior to randomization, the subject entered a washout period (if required) where anti-psoriatic treatment and other relevant medication/treatments were discontinued as defined by the exclusion criteria. The washout/screening period could last for up to 30 days, depending on which disallowed treatments the subject received.

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

The trial was an open-label trial evaluating the Safety and Pharmacokinetic profile of the MC2-01 cream.

Arms

Arm title	MC2-01 Cream

Arm description:

Calcipotriene/betamethasone (Calcipotriene/betamethasone dipropionate, w/w 0,005%/0,064%) cream. One application daily for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	MC2-01 Cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

MC2-01 (calcipotriene/betamethasone dipropionate, w/w 0,005%/0,064%) cream

Number of subjects in period 1	MC2-01 Cream
Started	7
Completed	6
Not completed	1
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	MC2-01 Cream
Reporting group description:	
Calcipotriene/betamethasone (Calcipotriene/betamethasone dipropionate, w/w 0,005%/0,064%) cream. One application daily for 8 weeks.	

Reporting group values	MC2-01 Cream	Total	
Number of subjects	7	7	
Age categorical Units: Subjects			
Adolescents (12-17 years)	7	7	
Age continuous Units: years			
arithmetic mean	14.7		
standard deviation	± 1.4	-	
Gender categorical Units: Subjects			
Female	4	4	
Male	3	3	
Fitzpatrick Skin Type Units: Subjects			
Skintype I	0	0	
Skintype II	2	2	
Skintype III	4	4	
Skintype IV	1	1	
Skintype V	0	0	
Skintype VI	0	0	

End points

End points reporting groups

Reporting group title	MC2-01 Cream

Reporting group description:

Calcipotriene/betamethasone (Calcipotriene/betamethasone dipropionate, w/w 0,005%/0,064%) cream. One application daily for 8 weeks.

Primary: Number of Participants With HPA (Hypothalamic-pituitary-adrenal) Axis Suppression at Week 4

End point title	Number of Participants With HPA (Hypothalamic-pituitary-adrenal) Axis Suppression at Week 4[1]

End point description:

Adrenal function will be assessed in a challenge test with an intravenous dose of cosyntropin. Measurement of serum cortisol levels pre- and post- stimulation is an accepted standard method used to evaluate adrenal suppression.

The test consists of an initial blood sampling. Following the blood sample, an intravenous bolus injection of 0.25 mg cosyntropin is given. The serum cortisol concentration 30 min. after will reflect stimulation of the adrenal glands induced by cosyntropin. HPA axis suppression is define as serum cortisol below 18 µg/dL

End point type	Primary

End point timeframe:

Change from Baseline to Week 4

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: The number and proportion of participants with HPA-axis suppression at Week 4 was summarized using frequency counts. As no HPA suppression was detected, statistical analysis on this parameter was not relevant.

End point values	MC2-01 Cream			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With HPA (Hypothalamic-pituitary-adrenal) Axis Suppression at Week 8

End point title	Number of Participants With HPA (Hypothalamic-pituitary-adrenal) Axis Suppression at Week 8[2]

End point description:

Adrenal function will be assessed in a challenge test with an intravenous dose of cosyntropin. Measurement of serum cortisol levels pre- and post- stimulation is an accepted standard method used to evaluate adrenal suppression.

The test consists of an initial blood sampling. Following the blood sample, an intravenous bolus injection of 0.25 mg cosyntropin is given. The serum cortisol concentration 30 min. after will reflect stimulation of

the adrenal glands induced by cosyntropin. HPA axis suppression is define as serum cortisol below 18 µg/dL

End point type	Primary

End point timeframe:

Change from Baseline to Week 8

Notes:

[2] - 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: The number and proportion of participants with HPA-axis suppression at Week 8 was summarized using frequency counts. As no HPA suppression was detected, statistical analysis on this parameter was not relevant.

End point values	MC2-01 Cream			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were collected/assessed from the time of the signature of the informed consent form by the subject and until the final follow-up visit.

Adverse event reporting additional description:

AEs that were considered related to the trial product would be followed until they were resolved, or until the medical condition was stable.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	MC2-01 Cream

Reporting group description:

Calcipotriene/betamethasone (Calcipotriene/betamethasone dipropionate, w/w 0,005%/0,064%) cream. One application daily for 8 weeks.

Serious adverse events	MC2-01 Cream		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (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	MC2-01 Cream		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1		
Tonsillitis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 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? Yes

Date	Interruption	Restart date
27 May 2020	Prematurely ended, due to challenges with recruiting subjects, not least due to COVID-19. Up to that point, 7 subjects had been enrolled in the trial; of them, 6 subjects already completed the trial and 1 subject had been withdrawn prematurely.	-

Notes:

Limitations and caveats

None reported