Clinical trial results:
An open label study to evaluate the efficacy and tolerability of erenumab in the prophylactic treatment of persistent headache attributed to mild traumatic injury to the head

Summary

EudraCT number	2018-003943-46
Trial protocol	DK
Global end of trial date	09 March 2021

Results information

Result version number	v1 (current)
This version publication date	28 March 2021
First version publication date	28 March 2021

Trial information

Trial identification

Sponsor protocol code	081018

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Danish Headache Center
Sponsor organisation address	V, Valdemar Hansensvej 5, Glostrup, Denmark, 2600
Public contact	Henrik Schytz, Danish Headache Center, 45 28761824, henrik.winther.schytz.01@regionh.dk
Scientific contact	Henrik Schytz, Danish Headache Center, 38633863 28761824, henrik.winther.schytz.01@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	06 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 March 2020
Global end of trial reached?	Yes
Global end of trial date	09 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of ERENUMAB on change in the monthly average number of headache days with moderate or severe intensity from baseline to week 9-12 in patients with persistent post-traumatic headache (PPTH)

To evaluate the effect of ERENUMAB on change in the monthly average number of headache days from baseline to week 9-12 in PPTH patients

Protection of trial subjects:

The study consisted of treatment of post-traumatic headache patients

Background therapy:

The same as investigated

Evidence for comparator:

N.A:

Actual start date of recruitment	01 February 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	100

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from the outpatient clinic of the Danish Headache Center and from neurological departments and rehabilitation centers in the Capital Region of
Denmark as well as the Region of Southern Denmark.

Pre-assignment

Screening details:

Patients included males and females aged 18 to 65 years with a history of persistent headache attributed to mild TBI.

Period 1

Period 1 title	4 weeks
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Active
Arm description: -	
Arm type	Active
Investigational medicinal product name	Erenumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

140 mg s.c.

Number of subjects in period 1	Active
Started	100
Completed	100

Period 2

Period 2 title	Week 12
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Week 9-12

Arms	
Arm title	Week 9-12
Arm description: -	
Arm type	Open label
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Week 9-12
Started	100
Completed	100

Baseline characteristics

End points

End points reporting groups

Reporting group title	Active
Reporting group description: -	
Reporting group title	Week 9-12
Reporting group description: -	

Primary: Primary

End point title	Primary
End point description: Mean change in number of monthly headache days of moderate to severe intensity	
End point type	Primary
End point timeframe: from baseline (4-week pretreatment period) to week 9–12	

End point values	Active	Week 9-12		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89[1]	89		
Units: headache days	89	89		

Notes:

[1] - None

Statistical analyses

Statistical analysis title	Descriptive
Statistical analysis description: See article	
Comparison groups	Active v Week 9-12
Number of subjects included in analysis	178
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	< 0.05
Method	descriptive
Parameter estimate	Descriptive

Notes:

[2] - see article

Adverse events

Adverse events information

Timeframe for reporting adverse events:

from first injection to week 9–12.

Adverse event reporting additional description:

Overall, 100 patients received at least one dose of erenumab and were included in the tolerability and safety analyses. Seventy-eight patients reported at least
one adverse event, with the most common ones being constipation (n = 30) and injection-site reactions (n = 15). Of the former, nine patients reported recurrent episodes of constipation

Assessment type	Systematic

Dictionary used

Dictionary name	Oxford
Dictionary version	1

Reporting groups

Reporting group title	All patients

Reporting group description: -

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (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	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 100 (30.00%)		
Gastrointestinal disorders			
Constiptation			
subjects affected / exposed	30 / 100 (30.00%)		
occurrences (all)	30		

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.

This was an open label study

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32493206