Clinical trial results:
Cerebrospinal fluid levels of triamcinolone acetonide

Summary

EudraCT number	2019-001863-60
Trial protocol	AT
Global end of trial date	08 November 2021

Results information

Result version number	v1 (current)
This version publication date	19 April 2023
First version publication date	19 April 2023
Summary attachment (see zip file)	Manuscript (Dahm V 2021 Triamcinolon acetonide can be detected in CSF.pdf)

Trial information

Trial identification

Sponsor protocol code	04/2019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04658836
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abteilung für Hals-, Nasen- und Ohrenkrankheiten MUW, AKH Wien
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	HNO Ambulanz 8J, Abteilung für Hals-, Nasen- und Ohrenkrankheiten MUW, AKH Wien, valerie.dahm@meduniwien.ac.at
Scientific contact	HNO Ambulanz 8J, Abteilung für Hals-, Nasen- und Ohrenkrankheiten MUW, AKH Wien, valerie.dahm@meduniwien.ac.at

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	07 February 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 February 2020
Global end of trial reached?	Yes
Global end of trial date	08 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objective
Demonstrate presence of Triamcinolone acetonide in cerebrospinal fluid

Protection of trial subjects:

Patients will be randomly assigned a three-digit number and the further data analysis will be carried out anonymously.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2019
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	Austria: 21
Worldwide total number of subjects	21
EEA total number of subjects	21

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)	17
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited over a time period of 2 years. The active phase of each patient lasted up to 9 days.

Pre-assignment

Screening details:

Patients were asked to be included in the study if they underwent a vestibular schwannoma resection

Period 1

Period 1 title	Vestibular schwannoma (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	CSF Triamcinolone

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intratympanic use

Dosage and administration details:

40mg/ml intratympanic injection

Number of subjects in period 1	CSF Triamcinolone
Started	21
Completed	21

Baseline characteristics

Reporting groups	
Reporting group title	Vestibular schwannoma

Reporting group description: -

Reporting group values	Vestibular schwannoma	Total	
Number of subjects	21	21	
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)	17	17	
From 65-84 years	4	4	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	13	13	
Male	8	8	

End points

End points reporting groups

Reporting group title	CSF Triamcinolone

Reporting group description: -

Primary: Triamcinolone levels in CSF

End point title	Triamcinolone levels in CSF[1]

End point description:

End point type	Primary

End point timeframe:

single measurement

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: Due to the small sample size of seven (SCC), nine (RWM) and twenty-one (CSF) samples, results are reported as individual data, mean and median, where appropriate. Median values (interquartile range, IQR) are given for description of continuous variables.

End point values	CSF Triamcinolone			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: nanogram(s)/millilitre				
number (not applicable)	21			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 2 years	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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 adverse events happened during the trial

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34864199