Clinical trial results:
Triamcinolone levels in cochlear perilymph

Summary

EudraCT number	2017-002377-19
Trial protocol	AT
Global end of trial date	30 June 2021

Results information

Result version number	v1 (current)
This version publication date	09 February 2024
First version publication date	09 February 2024
Summary attachment (see zip file)	Manuscript (Dahm V 2021 Evaluation of Levels of Triamcinolone Acetonide in Human Perilymph and Plasma After Intratympanic Application in Patients Receiving Cochlear Implants A Randomized Clinical Trial.pdf)

Trial information

Trial identification

Sponsor protocol code	1456/2017

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03248856
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,
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	30 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 March 2020
Global end of trial reached?	Yes
Global end of trial date	30 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objective
Demonstrate absorption of Triamcinolone acetonide in cochlear perilymph in comparison to dissemination to the blood circulation after intratympanic application

Protection of trial subjects:

Case report forms will be copied and stored separately. Data will be double-checked and saved in an excel sheet on a computer to which only study personel has access to. 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	02 October 2017
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	35
From 65 to 84 years	5

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients scheduled for cochlear implantation will be asked to participate in the study. Inclusion and exclusion criteria will be evaluated at the ent outpatients department. If patients fulfill inclusion and exclusion criteria and consent to the study is given a reevaluation on day 0 will be carried out. If the second evaluation has a positive o

Period 1

Period 1 title	Study patients (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1

Arm description:

(TAC, 10 mg/mL, 24 h before sampling)

Arm type	Active comparator
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:

intratympanic 10mg/ml

Arm title	Group 2

Arm description:

(TAC, 40 mg/mL, 24 h before sampling)

Arm type	Active comparator
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:

intratympanic 40mg/ml

Arm title	Group 3

Arm description:

(TAC, 10 mg/mL, 1 h before sampling)

Arm type	Active comparator

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:
intratympanic 10mg/ml

Arm title	Group 4

Arm description: -

Arm type	Active comparator
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:
intratympanic 40mg/ml

Number of subjects in period 1	Group 1	Group 2	Group 3
Started	10	10	10
Completed	10	10	10

Number of subjects in period 1	Group 4
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Study patients

Reporting group description: -

Reporting group values	Study patients	Total	
Number of subjects	40	40	
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)	35	35	
From 65-84 years	5	5	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	20	20	
Male	20	20	

End points

End points reporting groups	
Reporting group title	Group 1
Reporting group description: (TAC, 10 mg/mL, 24 h before sampling)	
Reporting group title	Group 2
Reporting group description: (TAC, 40 mg/mL, 24 h before sampling)	
Reporting group title	Group 3
Reporting group description: (TAC, 10 mg/mL, 1 h before sampling)	
Reporting group title	Group 4
Reporting group description: -	

Primary: TRiamcinolone levels	
End point title	TRiamcinolone levels
End point description:	
End point type	Primary
End point timeframe: single measurement	

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	10
Units: microgram(s)/microlitre				
number (not applicable)	46.4	96.8	396.4	329.4

Attachments (see zip file)	Dahm V 2021 Evaluation of Levels of Triamcinolone Acetonide

Statistical analyses	
Statistical analysis title	statistical analysis
Comparison groups	Group 2 v Group 3 v Group 4 v Group 1

Number of subjects included in analysis	40
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	ANOVA
Parameter estimate	Median difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
No adverse events reported	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

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

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 serious adverse events have been reported for intratympanic injection of triamcinolone acetonide

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