



## 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:

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**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:

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**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:

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**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:

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**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

|                                        |                         |
|----------------------------------------|-------------------------|
| <b>Arm title</b>                       | 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

|                                       |                   |
|---------------------------------------|-------------------|
| <b>Number of subjects in period 1</b> | 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<br>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<br>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 <sup>[1]</sup> |
| End point description: |                                            |

|                                            |         |
|--------------------------------------------|---------|
| End point type                             | Primary |
| End point timeframe:<br>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.

|                               |                      |  |  |  |
|-------------------------------|----------------------|--|--|--|
| <b>End point values</b>       | CSF<br>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

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

2 years

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

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### Dictionary used

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|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

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|                    |   |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

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

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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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

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