



## Clinical trial results: Intravitreal Lucentis (Ranibizumab) in acute central serous Chorioretinopathy - a prospective, randomized, single blind monocentric study

### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2010-020902-13    |
| Trial protocol           | AT                |
| Global end of trial date | 04 September 2014 |

### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 02 January 2021 |
| First version publication date | 02 January 2021 |

### Trial information

#### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | 0001-2010 |
|-----------------------|-----------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |                                                                                                                                                                     |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Medical University Innsbruck                                                                                                                                        |
| Sponsor organisation address | Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020                                                                                                    |
| Public contact               | RCS Studie, Chefsekretariat, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Innsbruck, +43 51250423720, bernhard.steger@i-med.ac.at |
| Scientific contact           | RCS Studie, Chefsekretariat, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Innsbruck, +43 51250423720, bernhard.steger@i-med.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                       | 04 September 2014 |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 04 September 2014 |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 04 September 2014 |
| Was the trial ended prematurely?                     | Yes               |

Notes:

---

**General information about the trial**

---

Main objective of the trial:

To test the safety and efficacy of intravitreal injections with Lucentis (Ranibizumab) in acute onset CSC. Primary outcome measure is the resolution of neurosensory detachment as measured by optic coherence tomography six months after study inclusion.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

|                                                           |              |
|-----------------------------------------------------------|--------------|
| Actual start date of recruitment                          | 01 July 2011 |
| 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: 99999 |
| Worldwide total number of subjects   | 99999          |
| EEA total number of subjects         | 99999          |

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)                      | 99999 |
| From 65 to 84 years                       | 0     |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

### Pre-assignment

Screening details:

N/A

### Period 1

|                              |                                   |
|------------------------------|-----------------------------------|
| Period 1 title               | Treatment period (overall period) |
| Is this the baseline period? | Yes                               |
| Allocation method            | Randomised - controlled           |
| Blinding used                | Single blind                      |
| Roles blinded                | Subject                           |

Blinding implementation details:

N/A

### Arms

|                                        |                   |
|----------------------------------------|-------------------|
| <b>Arm title</b>                       | Lucentis/ Placebo |
| Arm description: -                     |                   |
| Arm type                               | Experimental      |
| Investigational medicinal product name | Lucentis          |
| Investigational medicinal product code |                   |
| Other name                             | Ranibizumab       |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intravitreal use  |

Dosage and administration details:

Subjects would have received intravitreal injection of 0.5mg (0.05mL) Lucentis under sterile conditions up to three times during the whole trial.

|                                        |           |
|----------------------------------------|-----------|
| Investigational medicinal product name | Placebo   |
| Investigational medicinal product code |           |
| Other name                             |           |
| Pharmaceutical forms                   | Injection |
| Routes of administration               | Other use |

Dosage and administration details:

Subjects would have received a "sham-injection" of 0.05mL placebo under sterile conditions up to three times during the whole trial.

|                                       |                   |
|---------------------------------------|-------------------|
| <b>Number of subjects in period 1</b> | Lucentis/ Placebo |
| Started                               | 99999             |
| Completed                             | 99999             |



## Baseline characteristics

### Reporting groups

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Treatment period |
|-----------------------|------------------|

Reporting group description: -

| Reporting group values                                                          | Treatment period | Total |  |
|---------------------------------------------------------------------------------|------------------|-------|--|
| Number of subjects                                                              | 99999            | 99999 |  |
| Age categorical                                                                 |                  |       |  |
| No patients were enrolled in this trial. "99999" is a value for 0 participants. |                  |       |  |
| 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)                                                            | 99999            | 99999 |  |
| From 65-84 years                                                                | 0                | 0     |  |
| 85 years and over                                                               | 0                | 0     |  |
| Age continuous                                                                  |                  |       |  |
| No patients were enrolled in this trial. "99999" is a value for 0 participants. |                  |       |  |
| Units: years                                                                    |                  |       |  |
| arithmetic mean                                                                 | 0                |       |  |
| standard deviation                                                              | ± 0              | -     |  |
| Gender categorical                                                              |                  |       |  |
| No patients were enrolled in this trial. "99999" is a value for 0 participants. |                  |       |  |
| Units: Subjects                                                                 |                  |       |  |
| Female                                                                          | 99999            | 99999 |  |
| Male                                                                            | 0                | 0     |  |

## End points

### End points reporting groups

|                                |                   |
|--------------------------------|-------------------|
| Reporting group title          | Lucentis/ Placebo |
| Reporting group description: - |                   |

### Primary: Neurosensory detachment

|                                                                                                                                                                            |                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| End point title                                                                                                                                                            | Neurosensory detachment <sup>[1]</sup> |
| End point description:<br>Primary outcome measure is the resolution of neurosensory detachment as measured by optic coherence tomography six months after study inclusion. |                                        |
| End point type                                                                                                                                                             | Primary                                |
| End point timeframe:<br>6 months                                                                                                                                           |                                        |

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: No subjects were enrolled in this trial, therefore no statistical analysis was done.

| End point values            | Lucentis/<br>Placebo |  |  |  |
|-----------------------------|----------------------|--|--|--|
| Subject group type          | Reporting group      |  |  |  |
| Number of subjects analysed | 99999 <sup>[2]</sup> |  |  |  |
| Units: $\mu\text{m}$        |                      |  |  |  |
| number (not applicable)     | 99999                |  |  |  |

Notes:

[2] - No subjects were recruited for this trial. " 99999" is a value for 0 participants.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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

Timeframe for reporting adverse events:

01.07.2011- 04.09.2014

Adverse event reporting additional description:

No patients were included in this trial, therefore no AEs or SAEs were reported.

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

### Dictionary used

|                 |       |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

|                    |      |
|--------------------|------|
| Dictionary version | 4.03 |
|--------------------|------|

### Reporting groups

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | Lucentis/ Placebo |
|-----------------------|-------------------|

Reporting group description: -

| Serious adverse events                            | Lucentis/ Placebo |  |  |
|---------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events |                   |  |  |
| subjects affected / exposed                       | 0 / 99999 (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                            | Lucentis/ Placebo |  |  |
|-------------------------------------------------------|-------------------|--|--|
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 0 / 99999 (0.00%) |  |  |

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 subjects were enrolled in this trial, therefore no AEs or SAEs were observed.



## 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.

|                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No subjects were enrolled in this trial. "99999" is a value for 0 participants , as it was not possible to fill in "0" for the number of included patients. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

Notes: