



Clinical trial results:

Acetylic salicylic acid for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

A randomized, double-blind, placebo-controlled trial

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2010-022123-29 |
| Trial protocol | AT |
| Global end of trial date | 25 February 2014 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 27 July 2019 |
| First version publication date | 27 July 2019 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | ASA-COPD |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Medical University of Vienna |
| Sponsor organisation address | Währinger Gürtel 18-20, Vienna, Austria, 1090 |
| Public contact | Markus Zeitlinger, Md, Medical University of Vienna, Department of Clinical Pharmacology, 0043 14040029810, markus.zeitlinger@meduniwien.ac.at |
| Scientific contact | Markus Zeitlinger, Md, Medical University of Vienna, Department of Clinical Pharmacology, 0043 14040029810, markus.zeitlinger@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 | 25 February 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 December 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 February 2014 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of ASA as add-on therapy in COPD patients in comparison to placebo in spirometric and clinical regard, and to evaluate safety of this therapy.

Protection of trial subjects:

Subjects were under the supervision of a physician or an experienced nurse during the trial.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 06 June 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: 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) | 22 |
| From 65 to 84 years | 18 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from the Dep. of Pulmology, Medical University Vienna

Pre-assignment

Screening details:

Check of the in- and Exclusion criteria, Physical examination, Vital signs and Laboratory assessment

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|------------|
| Arm title | Study drug |
|------------------|------------|

Arm description:

Subjects will be randomized (1:1) to receive the study drug (ASA)

| | |
|--|----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ASS Genericon 500 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

ASS Genericon 500 mg, once daily for 12 weeks

| | |
|------------------|------------------|
| Arm title | Matching Placebo |
|------------------|------------------|

Arm description:

Subjects will be randomized (1:1) to receive a placebo administered QD orally for 12 weeks.

| | |
|--|-----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo tablets |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Placebo tablets without active substance (Fagron Barsbüttel, Germany) once daily for 12 weeks

| Number of subjects in period 1 | Study drug | Matching Placebo |
|---------------------------------------|------------|------------------|
| Started | 20 | 20 |
| Completed | 19 | 20 |
| Not completed | 1 | 0 |
| Physician decision | 1 | - |

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

| Reporting group values | Overall trial | 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) | 22 | 22 | |
| From 65-84 years | 18 | 18 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 16 | 16 | |
| Male | 24 | 24 | |

End points

End points reporting groups

| | |
|---|------------------|
| Reporting group title | Study drug |
| Reporting group description: Subjects will be randomized (1:1) to receive the study drug (ASA) | |
| Reporting group title | Matching Placebo |
| Reporting group description: Subjects will be randomized (1:1) to receive a placebo administered QD orally for 12 weeks. | |

Primary: Change in FEV1 after 12 weeks compared to baseline

| | |
|---------------------------------|--|
| End point title | Change in FEV1 after 12 weeks compared to baseline |
| End point description: | |
| End point type | Primary |
| End point timeframe: 8 hours | |

| End point values | Study drug | Matching Placebo | | |
|-----------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 20 | | |
| Units: Bq/ml | | | | |
| number (not applicable) | 19 | 20 | | |

Statistical analyses

| | |
|---|-------------------------------|
| Statistical analysis title | Endpoint analysis |
| Comparison groups | Study drug v Matching Placebo |
| Number of subjects included in analysis | 39 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.05 |
| Method | t-test, 2-sided |

Adverse events

Adverse events information

Timeframe for reporting adverse events:
from 06.Jun.2011 to 22.Dec.2013

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | overall trial |
|-----------------------|---------------|

Reporting group description: -

| Serious adverse events | overall trial | | |
|---|----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 40 (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 | overall trial | | |
|---|------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 27 / 40 (67.50%) | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | | |
| occurrences (all) | 11 | | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | | |
| occurrences (all) | 2 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | | |
| occurrences (all) | 2 | | |
| Gastrooesophageal reflux disease | | | |

| | | | |
|--|--|--|--|
| subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 4 | | |
| Respiratory, thoracic and mediastinal disorders Upper respiratory tract infection subjects affected / exposed occurrences (all) | 8 / 40 (20.00%) 9 | | |
| Bronchitis subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | | |
| Chronic obstructive pulmonary disease | Additional description: Exacerbation of the underlying disease | | |
| subjects affected / exposed occurrences (all) | 25 / 40 (62.50%) 25 | | |
| Renal and urinary disorders Urinary tract infection subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | | |
| Musculoskeletal and connective tissue disorders Neck pain subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | | |
| Infections and infestations Rhinitis subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | | |
| Pharyngitis subjects affected / exposed occurrences (all) | 2 / 40 (5.00%) 2 | | |

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? Yes

| Date | Interruption | Restart date |
|------------------|---|--------------|
| 25 February 2014 | The Interim Analysis has shown sufficient data for premature Termination of the clinical Trial. | - |

Notes:

Limitations and caveats

None reported