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