



Clinical trial results:
Biological Standardization of Ambrosia elatior (ragweed) Allergen Extract.
Determination of the Biological Activity in HEP units.
An Open Monocenter Study.

Summary

EudraCT number	2011-002096-42
Trial protocol	DE
Global end of trial date	10 December 2013

Results information

Result version number	v1 (current)
This version publication date	10 May 2018
First version publication date	10 May 2018
Summary attachment (see zip file)	Standardization Ambrosia elat. (2) Summary (6057-PR-PRI-188.pdf)

Trial information

Trial identification

Sponsor protocol code	6057-PR-PRI-188
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	LETI Pharma GmbH
Sponsor organisation address	Stockumer Str. 28, Witten, Germany, 58453
Public contact	Medical Department, LETI Pharma GmbH, 0049 02302202860,
Scientific contact	Medical Department, LETI Pharma GmbH, 0049 02302202860,

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	08 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 December 2013
Global end of trial reached?	Yes
Global end of trial date	10 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To identify the concentration of a native *Ambrosia elatior* extract inducing the same wheal size as provoked by 10mg/ml Histamine hydrochloride

Protection of trial subjects:

Each potential subject was adequately informed of the aims, method, anticipated benefits and potential hazards of the study and the discomfort that it might entail. All of them were informed that they were free to participate in the study and stop their participation at any time. Participants had the opportunity to make all kind of questions about the study, and every subject confirmed his or her participation by filling in and signing the informed consent form. Written informed consent was obtained from each subject prior to the performance of any study-specific procedures.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 September 2012
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	Germany: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

30 patients enrolled, 30 patients were eligible and received study medication (ITT).

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	treatment arm
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Arm description:

Only one arm, all patients received Ambrosia elatior skin prick test.

Arm type	Experimental
Investigational medicinal product name	Prick Test Ambrosia elatior
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for skin-prick test
Routes of administration	Cutaneous use

Dosage and administration details:

Prick Test Ambrosia elatior LETI at 15, 10, 1.0, 0.1 and 0.01 mg/mL, positive control (histamine dihydrochloride(10mg/mL)), negative control (glycerinated phenol saline solution).

Number of subjects in period 1	treatment arm
Started	30
Completed	30

Baseline characteristics

End points

End points reporting groups

Reporting group title	treatment arm
Reporting group description: Only one arm, all patients received Ambrosia elatior skin prick test.	
Subject analysis set title	treatment arm (PP)
Subject analysis set type	Per protocol
Subject analysis set description: A total of 30 patients were enrolled in 1 study site in Germany. A total number of 30 patients received the study medication (ITT population/Safety population). Nine of them were excluded after receiving the study medication from the PP population (n = 21) since they did not meet Nordic Guideline criteria.	

Primary: wheal size area

End point title	wheal size area ^[1]
End point description:	
End point type	Primary
End point timeframe: 2 hours	
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: Primary efficacy endpoint was the wheal size area (mm ²) provoked on skin, by all tested allergen concentrations and histamine, at the site of puncture during the immediate phase in the patient analysed population. This endpoint was used to estimate the concentration of Ambrosia elatior allergen extract that elicits a wheal of the same size as the positive control. Analysis has been performed using a protected spreadsheet (Excel) designed specifically to analyse Standardization clinical trials.	

End point values	treatment arm	treatment arm (PP)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	21	21		
Units: mm				
geometric mean (standard deviation)	16958.51 (± 75012.57)	16958.51 (± 75012.57)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From screening until 48 hours after test.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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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 adverse events were reported in the clinical trial.

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