



Clinical trial results:

A Randomized, Double Blind, Placebo Controlled Multicenter Study to Assess the Efficacy and Safety of nasal spray ANTIRIN® and NASIC® in the Treatment of Allergic Rhinitis.

Summary

EudraCT number	2006-000435-99
Trial protocol	CZ
Global end of trial date	14 September 2007

Results information

Result version number	v1 (current)
This version publication date	14 July 2016
First version publication date	14 July 2016

Trial information

Trial identification

Sponsor protocol code	03/06/OXD/TP3
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zentiva k.s
Sponsor organisation address	U kabelovny 130 , Praha 10 - Dolní Měcholupy, Czech Republic, 102 37
Public contact	MUDr. Tomas Hauser, Zentiva k.s, 00420 267243451, Tomas.Hauser@sanofi.com
Scientific contact	MUDr. Tomas Hauser, Zentiva k.s, 00420 267243451, Tomas.Hauser@sanofi.com

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	14 September 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 September 2007
Global end of trial reached?	Yes
Global end of trial date	14 September 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine if the study drug ANTIRIN® is at least as effective (non inferiority testing) assessed by TNSS changes after 4 day-therapy as the comparative product NASIC® in the treatment of allergic rhinitis and to compare ANTIRIN® with placebo to prove its efficacy and to compare NASIC® to placebo to prove assay sensitivity.

Protection of trial subjects:

No specific measurements required

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	12 June 2006
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	Czech Republic: 212
Worldwide total number of subjects	212
EEA total number of subjects	212

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)	212
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

June 12, 2006

15 center in Czech republic

Pre-assignment

Screening details:

inclusion/exclusion criteria check-list, medical history/ physical examination, laboratory examination: clinical chemistry, urinalysis, haematology, serology

Period 1

Period 1 title	Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	ANTIRIN

Arm description:

This arm includes subjects receiving ANTIRIN as a study medication.

Arm type	Experimental
Investigational medicinal product name	ANTIRIN
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

0.05 mg of oxymetazolin, 2.0 mg of dexpanthenolum, spray was administered 3 times per day into each nostril in horizontal position. One administration is one dose of spray into each nostril (0.1 ml of solution, 0.1 g).

Arm title	NASIC
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Arm description:

This arm includes subjects receiving NASIC as a study medication.

Arm type	Active comparator
Investigational medicinal product name	NASIC
Investigational medicinal product code	NA
Other name	NA
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

0.05 mg of oxymetazolin, 2.0 mg of dexpanthenolum, spray was administered 3 times per day into each nostril in horizontal position. One administration is one dose of spray into each nostril (0.1 ml of solution, 0.1 g).

Arm title	Placebo
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Arm description:

This arm includes subjects receiving placebo as a study medication.

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	NA
Other name	NA
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

0 mg of oxymetazolin, 0 mg of dexpanthenolum, spray was administered 3 times per day into each nostril in horizontal position. One administration is one dose of spray into each nostril (0.1 ml of solution, 0.1 g).

Number of subjects in period 1	ANTIRIN	NASIC	Placebo
Started	69	72	71
Completed	67	70	68
Not completed	2	2	3
Protocol deviation	2	2	3

Baseline characteristics

Reporting groups

Reporting group title	ANTIRIN
Reporting group description:	
This arm includes subjects receiving ANTIRIN as a study medication.	
Reporting group title	NASIC
Reporting group description:	
This arm includes subjects receiving NASIC as a study medication.	
Reporting group title	Placebo
Reporting group description:	
This arm includes subjects receiving placebo as a study medication.	

Reporting group values	ANTIRIN	NASIC	Placebo
Number of subjects	69	72	71
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	69	72	71
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	27.942	30.861	29.31
standard deviation	± 8.352	± 9.761	± 9.816
Gender categorical			
Units: Subjects			
Female	43	42	41
Male	26	30	30

Reporting group values	Total		
Number of subjects	212		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	212		

From 65-84 years	0		
85 years and over	0		

Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	126		
Male	86		

End points

End points reporting groups

Reporting group title	ANTIRIN
Reporting group description: This arm includes subjects receiving ANTIRIN as a study medication.	
Reporting group title	NASIC
Reporting group description: This arm includes subjects receiving NASIC as a study medication.	
Reporting group title	Placebo
Reporting group description: This arm includes subjects receiving placebo as a study medication.	

Primary: TNSS change

End point title	TNSS change ^[1]
End point description:	
End point type	Primary
End point timeframe: comparison of data from the whole study period	
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: NA	

End point values	ANTIRIN	NASIC	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	71	70	
Units: TNSS				
arithmetic mean (standard error)	-2.448 (± 0.326)	-3.155 (± 0.339)	-3.514 (± 0.332)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:
assessment for whole study period

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	10.1

Reporting groups

Reporting group title	ANTIRIN
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Reporting group description:

This arm includes subjects receiving ANTIRIN as a study medication.

Reporting group title	NASIC
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Reporting group description:

This arm includes subjects receiving NASIC as a study medication.

Reporting group title	Placebo
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Reporting group description:

This arm includes subjects receiving placebo as a study medication.

Serious adverse events	ANTIRIN	NASIC	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 69 (0.00%)	0 / 72 (0.00%)	0 / 71 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ANTIRIN	NASIC	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 69 (15.94%)	6 / 72 (8.33%)	6 / 71 (8.45%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 69 (2.90%)	0 / 72 (0.00%)	2 / 71 (2.82%)
occurrences (all)	4	4	0
General disorders and administration site conditions			
Oedema mucosal			
subjects affected / exposed	1 / 69 (1.45%)	0 / 72 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	1	1

Application site irritation subjects affected / exposed occurrences (all)	0 / 69 (0.00%) 1	1 / 72 (1.39%) 1	0 / 71 (0.00%) 1
Eye disorders Conjunctival hyperaemia subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 1	0 / 72 (0.00%) 0	0 / 71 (0.00%) 0
Gastrointestinal disorders Oral discomfort subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 1	0 / 72 (0.00%) 1	0 / 71 (0.00%) 1
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	2 / 69 (2.90%) 2	0 / 72 (0.00%) 0	0 / 71 (0.00%) 0
Nasal discomfort subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 4	2 / 72 (2.78%) 4	1 / 71 (1.41%) 4
Rhinorrhoea subjects affected / exposed occurrences (all)	2 / 69 (2.90%) 2	0 / 72 (0.00%) 2	0 / 71 (0.00%) 2
Sneezing subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 4	2 / 72 (2.78%) 4	1 / 71 (1.41%) 4
Pharyngolaryngeal discomfort subjects affected / exposed occurrences (all)	0 / 69 (0.00%) 1	1 / 72 (1.39%) 1	0 / 71 (0.00%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 69 (0.00%) 2	0 / 72 (0.00%) 2	2 / 71 (2.82%) 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? No

Limitations and caveats

None reported