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- Trial identification
- Workflow information
- Sponsor identification
- Information on the IMP/placebo
- Information on the trial
- Population of trial subjects

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- Ergebnisberichte

Bei dem nachfolgenden Ergebnisbericht handelt es sich um Daten des pharmazeutischen Unternehmers, der Inhaber der Zulassung des Test-Pruefpraeparates ist, oder des Sponsors

2010-023227-26

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2010-023227-26 Randomized, prospective double-blinded study to evaluate safety and efficacy of Angocin Anti-Infekt N versus placebo in the prophylaxis of respiratory tract infections

Entry in CT-Database (OFF):

Trial identification

EudraCT number:	2010-023227-26
Full title of the trial:	Randomized, prospective double-blinded study to evaluate safety and efficacy of Angocin Anti-Infekt N versus placebo in the prophylaxis of respiratory tract infections
Abbreviated title:	AngoPA
Sponsor's protocol code number:	Repha_1352
Trial part of a PIP:	Not answered

Workflow information of National Competent Authority

Zuständige Behörde:	BfArM
Bescheiddatum Bundesoberbehörde:	20101202
Bescheidart Bundesoberbehörde:	Genehmigung
Bescheiddatum Ethikkommission:	20101217
Bescheidart Ethikkommission:	positiv
Stand der Studie/Art:	Beendigung
Datum/Ende der Studie in Deutschland:	20110502

Sponsor identification

Sponsor

Status of the Sponsor: Commercial

Repha GmbH
Germany

Information on the investigational medicinal product(s)/placebo(s)

1: (PR1)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation:	Y
Trade name:	Angocin Anti-Infekt N
Name of marketing authorisation holder:	Repha GmbH
Marketing authorisation granted by:	Germany

IMP - Description of the investigational medicinal product

Pharmaceutical form:	Film-coated tablet
Specific paediatric formulation:	Not answered
Route of administration:	Oral use

Active substance-INN / proposed INN:	Nasturtium herb powder
Active substance - CAS number:	n.a.

Active substance - current sponsor code:	n.a.
Active substance - other descriptive name:	Nasturtium herb powder
Concentration type:	exact number
Concentration number part 1:	200
Concentration unit:	mg milligram(s)
Active substance-INN / proposed INN:	Horseradish root powder
Active substance - CAS number:	n.a.
Active substance - current sponsor code:	n.a.
Active substance - other descriptive name:	Horseradish root powder
Concentration type:	exact number
Concentration number part 1:	80
Concentration unit:	mg milligram(s)

IMP - Type of the IMP

Acitve substance origin - biological / biotechnological:	Y
Medicinal product type - herbal:	Y

IMP - Regulatory information

Orphan drug designation in the Community:	N

Placebo - Information on the placebo(s)

Placebo in this trial:	Y

1: (PL1)

Placebo - pharmaceutical form:	Film-coated tablet
Placebo - route of administration:	Oral use

Information on the trial

General information on the trial

Medical condition:	Prophylaxis of respiratory tract infections

MedDRA:	MedDRA version code	MedDRA level	MedDRA classification code	MedDRA term
	12.1	LLT	10066740	Acute respiratory tract infection

Rare disease:	N
Main objective of the trial:	Number of subjects with a respiratory tract infection during prophylactic administration within the three groups
Secondary objectives of trial:	Kind of infection, intensity of the infection and duration of the infection that occurs within the trial
Sub-study:	N
Principal inclusion criteria:	Adult volunteers of both sexes who have suffered in the previous cold season at least 2 acute infection of the respiratory tract, subjects aged 18 to 75 years,signed ICF (informed consent form)
Principal exclusion criteria:	serious chronic diseases, serious diseases of the psyche, known hypersensitivity to any of the components of the study medication,simultaneous participation in a clinical study or participation in a clinical trial within the previous 30 days before enrollment,pregnant women, nursing mothers or women planning a pregnancy, women of childbearing age who operate no adequate contraception,subjects with a disease or in a situation that exposed the opinion of the investigator the subjects a significant risk of prejudice the study results or influence them significantly,abnormal laboratory values,taking antibiotics within 3 weeks prior to study implementation,chronic infections of the respiratory tract,allergic rhinitis,influenza and pneumonia vaccine during the studyalcohol and drug abusesprevious participation in a study within the last 30 dayspregnancy and lactationknown hypersensitivity of one of the ingredients of the IMP and placebo
Primary endpoints:	The change of the number of subjects with a respiratory tract infection from the beginning to the end of the study in the three application groups.

Trial scope

Scope - diagnosis:	N
Scope - prophylaxis:	Y
Scope - therapy:	N
Scope - safety:	Y

Scope - efficacy:	Y
Scope - pharmacokinetic:	N
Scope - pharmacodynamic:	N
Scope - bioequivalence:	N
Scope - dose response:	Y
Scope - pharmacogenetic:	N
Scope - pharmacogenomic:	N
Scope - pharmacoeconomic:	N
Scope - others:	N

Trial phase and type

Trial phase - Phase I:	N
First administration to humans:	N
Bioequivalence study:	N
Other type of study:	N
Trial phase - Phase II:	N
Trial phase - Phase III:	Y
Trial phase - Phase IV:	N

Trial design

Trial design - controlled:	Y
Trial design - open:	N
Trial design - randomised:	Y
Trial design - single blind:	N
Trial design - double blind:	Y
Trial design - parallel group:	Y
Trial design - cross over:	N
Trial design - other:	N
Trial design - controlled/comparator other medicinal product:	N
Trial design - controlled/comparator placebo:	Y
Trial design - controlled/comparator other:	N
Single site in Member State:	N
Multiple sites in Member State:	Y
Number of sites anticipated in the Member State concerned:	4
Multiple Member States:	N
3rd Countries involved - trial conducted both within and outside EEA:	N
3rd Countries involved - trial conducted completely outside the EEA:	Not answered
Data monitoring committee in this trial:	N
Definition of the end of the trial:	provided in the protocol
Initial estimate of trial duration in this Member State - years:	0
Initial estimate of trial duration in this Member State - months:	3
Initial estimate of trial duration in this Member State - days:	26
Initial estimate of trial duration worldwide - years:	0
Initial estimate of trial duration worldwide - months:	3
Initial estimate of trial duration worldwide - days:	26

Population of trial subjects

Age span

Less than 18 years:	N
In utero:	N
Preterm newborn infants (gestational age less than 37 weeks):	N
Newborn (0 - 27 days):	N

Infant and toddler (28 days - 23 months):	N
Children (2 - 11 years):	N
Adolescents (12 - 17 years):	N
Adults (18 - 64 years):	Y
Elderly (>= 65 years):	Y

Gender

Gender - male:	Y
Gender - female:	Y

Group of trial subjects

Subject - healthy volunteers:	Y
Subjects - patients:	N
Subjects - specific vulnerable populations:	Y
Subjects - women of child-bearing potential not using contraceptives (s. Hinweis auf der Webseite):	N
Subjects - women of child-bearing potential using contraceptives:	Y
Subjects - pregnant women:	N
Subjects - nursing women:	N
Subjects - emergency situation:	N
Subjects incapable of giving consent personally:	N
Subjects - other types of subjects:	N

Planned number of trial subjects

Number of subjects in this Member State:	324

Plans for the treatment or care of subjects after the trial

is provided in the protocol

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