Clinical trial results:
Multiple site, randomized, prospective, open comparison of new locally used benzydamine product efficacy with reference product in adult patients with acute pharyngitis or tonsillitis which do not require antibiotic therapy

Summary

EudraCT number	2008-002042-38
Trial protocol	PL
Global end of trial date	04 March 2010

Results information

Result version number	v1 (current)
This version publication date	05 May 2021
First version publication date	05 May 2021

Trial information

Trial identification

Sponsor protocol code	AAR1/1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zakłady Farmaceutyczne „UNIA” Sp. Pracy
Sponsor organisation address	Chłodna 56/60, Warsaw, Poland, 00-872
Public contact	Ewa Golańska-Dutka, Zakłady Farmaceutyczne „UNIA” Sp. Pracy, 48 693400000, ewa.golanska@uniapharm.pl
Scientific contact	Ewa Golańska-Dutka, Zakłady Farmaceutyczne „UNIA” Sp. Pracy, 48 693400000, ewa.golanska@uniapharm.pl

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	04 March 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 March 2010
Global end of trial reached?	Yes
Global end of trial date	04 March 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To indicate that new benzydamine hydrochloride product used locally 4 to 6 times daily is equally effective as reference product in acute pharyngitis or tonsillitis in adult patients

Protection of trial subjects:

Treated in routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 October 2008
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	Poland: 109
Worldwide total number of subjects	109
EEA total number of subjects	109

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)	109
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients age 18-70 years old from Poland with acute pharyngitis with no need of using antibiotics, lasts form maximum 72 hours.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	109
Number of subjects completed	109

Period 1

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

Arms

Arm title	Patients with pharyngitis

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Uniben
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal spray, solution
Routes of administration	Oromucosal use

Dosage and administration details:

5 days, 4-6 times a day

Number of subjects in period 1	Patients with pharyngitis
Started	109
Completed	109

Baseline characteristics

Reporting groups	
Reporting group title	overal trial

Reporting group description: -

Reporting group values	overal trial	Total	
Number of subjects	109	109	
Age categorical Units: Subjects			
Adults (18-64 years)	109	109	
Gender categorical Units: Subjects			
Female	66	66	
Male	43	43	

End points

End points reporting groups

Reporting group title	Patients with pharyngitis

Reporting group description: -

Primary: intensification of symptoms according to indications

End point title	intensification of symptoms according to indications[1]

End point description:

The severity of the indications was assessed on a five-point symptom severity scale. The sum of the points obtained was defined as the total symptom index and subjected to statistical analysis. The absolute value of this parameter was assessed, as well as its changes in the time of consecutive visits of controls compared to visit 1.

End point type	Primary

End point timeframe:

from first to last visit

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: No control group. Statistical analysic was performed on 1 group:
Statistical methods:
• set significance level $p \leq 0.05$
• the normality of the distribution of the assessed parameters was assessed with the Shapiro-Wilk test
• statistical inference and comparison of clinical efficacy parameters were performed at $p < 0.05$ using the Wilcoxon and Kolmogorow-Smirnov tests
• the comparison of clinical efficacy parameters was carried out using the Wilcoxon and t-Student test

End point values	Patients with pharyngitis			
Subject group type	Reporting group			
Number of subjects analysed	109			
Units: 1-5				
number (not applicable)	109			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: During whole trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Frequency threshold for reporting non-serious adverse events: 1 %

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 non-serious adverse drug reaction reported during the time of 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