Clinical trial results:
An open-label, randomized, multicenter, two-arm efficacy and safety study of 14 days treatment with Finafloxacin 400 mg b.i.d. plus Amoxicillin 1000 mg b.i.d. versus Finafloxacin 400 mg b.i.d. plus Esomeprazole 40 mg b.i.d. in patients with Helicobacter pylori infection
Finafloxacin in patients with Helicobacter: FLASH study

Summary

EudraCT number	2007-007749-11
Trial protocol	DE
Global end of trial date	19 December 2008

Results information

Result version number	v1 (current)
This version publication date	07 July 2018
First version publication date	07 July 2018

Trial information

Trial identification

Sponsor protocol code	FINA-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00723502
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MerLion Pharmaceuticals GmbH
Sponsor organisation address	Robert-Roessle-Str. 10, Berlin, Germany, 13125
Public contact	Head Regulatory Affairs, MerLion Pharmaceuticals GmbH, lueckermann@merlionpharma.de
Scientific contact	Head Regulatory Affairs, MerLion Pharmaceuticals GmbH, lueckermann@merlionpharma.de

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	26 June 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 December 2008
Global end of trial reached?	Yes
Global end of trial date	19 December 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to compare the H. pylori eradication rates of 14-day treatment with finafloxacin in combination with amoxicillin or esomeprazole.

Protection of trial subjects:

Exclusion of subjects showing clinically significant abnormal vital signs or laboratory data at screening.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 August 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	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)	24
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening includes after signing of informed consent form Urea Breath Test and gastroscopy for performing Rapid Urea Test.

Period 1

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

Blinding implementation details:

No blinding was performed, as this was an open-label study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Finafloxacin/Amoxicillin

Arm description:

Finafloxacin twice daily + Amoxicillin twice daily

Arm type	Experimental
Investigational medicinal product name	Finafloxacin hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

400 mg twice daily [b.i.d. (8 X 50 mg tablets)] immediately after meal

Investigational medicinal product name	Amoxicillin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

1000 mg b.i.d. (as one 1000 mg tablet) immediately after meal.

Arm title	Finafloxacin/Esomeprazole

Arm description:

Finafloxain twice daily + Esomeprazole twice daily

Arm type	Experimental
Investigational medicinal product name	Finafloxacin hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

400 mg twice daily [b.i.d. (8 X 50 mg tablets)] immediately after meal

Investigational medicinal product name	Esomeprazole
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Gastro-resistant tablet
Routes of administration	Oral use

Dosage and administration details:

40 mg b.i.d. (as one 40 mg tablet) at least one hour before meal

Number of subjects in period 1	Finafloxacin/Amoxicillin	Finafloxacin/Esomeprazole
Started	15	15
Completed	15	15

Baseline characteristics

End points

End points reporting groups

Reporting group title	Finafloxacin/Amoxicillin
Reporting group description: Finafloxacin twice daily + Amoxicillin twice daily	
Reporting group title	Finafloxacin/Esomeprazole
Reporting group description: Finafloxain twice daily + Esomeprazole twice daily	

Primary: Efficacy - Eradication H. pylori

End point title	Efficacy - Eradication H. pylori[1]
End point description: The primary efficacy endpoint was the H. pylori eradication rate at Visit 4 (Day 45) in the finafloxacin plus amoxicillin and finafloxacin plus esomeprazole treatment groups after a 14 day treatment period.	
End point type	Primary
End point timeframe: Treatment start to day 45	

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: For both treatment groups, the H. pylori eradication rates were determined and also the respective 90% and 95% two-sided confidence intervals. Additionally, the difference in H. pylori eradication rates was estimated and the respective 90% and 95% two-sided confidence interval was determined in order to get an impression of a possible difference in rates.As this is a proof-of-concept study, all results were interpreted in an exploratory sense to get evidence of the H. pylori eradication rates.

End point values	Finafloxacin/Amoxicillin	Finafloxacin/Esomeprazole		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: percent				
number (confidence interval 95%)	26.7 (4.3 to 49)	60 (35.2 to 84.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Treatment start (day 1) to day 45 - 52	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	11.1
Reporting groups	
Reporting group title	Verum

Reporting group description: -

Serious adverse events	Verum		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Oophoritis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Verum		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 30 (80.00%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastrointestinal disorders			

Anal pruritus subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Burning mouth syndrome subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Constipation subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	8 / 30 (26.67%) 8		
Dyspepsia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Flatulence subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Tongue disorder subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Reproductive system and breast disorders Vulvovaginal pruritus subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Rash subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Oral candidiasis subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Vaginal infection subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 August 2008	Shelf life extension
01 September 2008	Correction of numbers of biopsy samples.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported