



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:

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

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