



Clinical trial results:

Preference for a prefilled syringe or Smartject™ device for delivering SIMPONI (golimumab) in patients suffering from moderate to severe ulcerative colitis (SMART)

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2014-000656-29 |
| Trial protocol | BE |
| Global end of trial date | 05 October 2015 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 10 September 2016 |
| First version publication date | 10 September 2016 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | MK-8259-027 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02155335 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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 | 05 October 2015 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 October 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to determine whether participants with ulcerative colitis prefer to administer golimumab using the SmartJect® autoinjector, using a prefilled syringe, or are undecided.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 01 July 2014 |
| 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 | Belgium: 100 |
| Worldwide total number of subjects | 100 |
| EEA total number of subjects | 100 |

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) | 93 |
| From 65 to 84 years | 6 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Anti-Tumor necrosis factor (TNF) naïve with established diagnosis of ulcerative colitis (UC) and anti-TNF experienced adults with established diagnosis of UC were enrolled in the study. Other inclusion and exclusion criteria applied.

Period 1

| | |
|------------------------------|----------------|
| Period 1 title | Period 1 |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Prefilled SyringeSmartject™ Device |

Arm description:

Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Prefilled Syringe delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg subcutaneous injection using prefilled syringe

| | |
|--|--|
| Investigational medicinal product name | Smartject Device delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg solution for subcutaneous injection using Smartject Device.

| | |
|------------------|-------------------------------------|
| Arm title | Smartject™ Device Prefilled Syringe |
|------------------|-------------------------------------|

Arm description:

Golimumab 50 mg supplied in a Smartject administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied a prefilled syringe 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Prefilled Syringe delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg subcutaneous injection using prefilled syringe

| | |
|--|--|
| Investigational medicinal product name | Smartject Device delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg solution for subcutaneous injection using Smartject Device.

| Number of subjects in period 1 | Prefilled SyringeSmartject™ Device | Smartject™ Device Prefilled Syringe |
|--------------------------------|------------------------------------|-------------------------------------|
| Started | 50 | 50 |
| Treated | 50 | 49 |
| Completed | 50 | 49 |
| Not completed | 0 | 1 |
| Withdrew prior to treatment | - | 1 |

Period 2

| | |
|------------------------------|----------------|
| Period 2 title | Period 2 |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Prefilled SyringeSmartject™ Device |

Arm description:

Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Prefilled Syringe delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg subcutaneous injection using prefilled syringe

| | |
|--|--|
| Investigational medicinal product name | Smartject Device delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Golimumab 50 mg solution for subcutaneous injection using Smartject Device.

| | |
|--|--|
| Arm title | Smartject™ Device Prefilled Syringe |
| Arm description: | |
| Golimumab 50 mg supplied in a Smartject administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied a prefilled syringe 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab. | |
| Arm type | Experimental |
| Investigational medicinal product name | Smartject Device delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Golimumab 50 mg solution for subcutaneous injection using Smartject Device. | |
| Investigational medicinal product name | Prefilled Syringe delivery of Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: | |
| Golimumab 50 mg subcutaneous injection using prefilled syringe | |

| Number of subjects in period 2 | Prefilled SyringeSmartject™ Device | Smartject™ Device Prefilled Syringe |
|---------------------------------------|------------------------------------|-------------------------------------|
| Started | 50 | 49 |
| Completed | 50 | 49 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Period 1 |
|-----------------------|----------|

Reporting group description: -

| Reporting group values | Period 1 | Total | |
|-------------------------|----------|-------|--|
| Number of subjects | 100 | 100 | |
| Age Categorical | | | |
| Units: Subjects | | | |
| Between 18 and 65 years | 93 | 93 | |
| >=65 years | 7 | 7 | |
| Gender Categorical | | | |
| Units: Subjects | | | |
| Female | 43 | 43 | |
| Male | 57 | 57 | |

End points

End points reporting groups

| | |
|---|-------------------------------------|
| Reporting group title | Prefilled SyringeSmartject™ Device |
| Reporting group description: Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab. | |
| Reporting group title | Smartject™ Device Prefilled Syringe |
| Reporting group description: Golimumab 50 mg supplied in a Smartject administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied a prefilled syringe 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab. | |
| Reporting group title | Prefilled SyringeSmartject™ Device |
| Reporting group description: Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab. | |
| Reporting group title | Smartject™ Device Prefilled Syringe |
| Reporting group description: Golimumab 50 mg supplied in a Smartject administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied a prefilled syringe 2 times, first by the physician and then by the participant. Participants receive a total of 200 mg of golimumab. | |
| Subject analysis set title | Per Protocol Set |
| Subject analysis set type | Per protocol |
| Subject analysis set description: All enrolled participants who met all inclusion and none of the exclusion criteria, received all four injections of golimumab according to the protocol, and completed the device preference questionnaire. | |

Primary: Percentage of Participants Who Prefer Prefilled Syringe, Smartject™ Device, or are Undecided (Day of Injections)

| | |
|--|---|
| End point title | Percentage of Participants Who Prefer Prefilled Syringe, Smartject™ Device, or are Undecided (Day of Injections) ^[1] |
| End point description: Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant is then administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Following the completion of the last injection, the participants completed a questionnaire in which they indicated if they preferred the syringe, the Smartject or were undecided as to which they preferred. | |
| End point type | Primary |
| End point timeframe: Day 0 (post last injection) | |

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 statistical analysis was planned for this endpoint.

| End point values | Per Protocol Set | | | |
|-----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 91 | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | | | | |
| Preferred Prefilled Syringe | 20.9 | | | |
| Preferred Smatject Device | 76.9 | | | |
| Undecided | 2.2 | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Prefer Prefilled Syringe, Smartject™ Device, or are Undecided (2 weeks Post Injections)

| | |
|-----------------|---|
| End point title | Percentage of Participants Who Prefer Prefilled Syringe, Smartject™ Device, or are Undecided (2 weeks Post Injections) ^[2] |
|-----------------|---|

End point description:

Golimumab 50 mg supplied in a prefilled syringe administered 2 times (once by the treating physician and then by the participant under the supervision of the treating physician). Participant then is administered Golimumab 50 mg supplied in the Smartject 2 times, first by the physician and then by the participant. Participants completed a questionnaire 2 weeks after the injections in which they indicated if they preferred the syringe, the Smartject or were undecided as to which they preferred.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 14 (2 weeks post injections)

Notes:

[2] - 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 statistical analysis was planned for this endpoint.

| End point values | Per Protocol Set | | | |
|-----------------------------------|----------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 91 | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | | | | |
| Preferred Prefilled Syringe | 26.4 | | | |
| Preferred Smatject Device | 71.4 | | | |
| Undecided | 2.2 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

up to 14 days post injections

Adverse event reporting additional description:

Population included all participants who received at least 1 injection of golimumab and were reported as 1 treatment group regardless of injection sequence.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | All Treated Participants |
|-----------------------|--------------------------|

Reporting group description:

All participants who received at least 1 injection from either prefilled syringe or Smartject

| Serious adverse events | All Treated Participants | | |
|---|--------------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 99 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | All Treated Participants | | |
|---|--------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 99 (0.00%) | | |

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: None of the reported non-serious adverse events eclipsed the 5% frequency threshold.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 23 March 2015 | Amendment 1: Primary reason for the amendment was to clarify the criteria that had to be met prior to initiating first line anti-TNF treatment. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported