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 golimumbab.

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 subcuntaneous 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 golimumbab.

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 subcuntaneous 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 golimumbab.

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 subcuntaneous 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 golimumbab.

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 subcuntaneous 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 golimumbab.

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 golimumbab.

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 golimumbab.

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 golimumbab.

Subject analysis set title	Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

All enrolled participants who met all inclusionand none of the exclusion criteria, receivedall 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 Particpants				
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 treatingphysician). 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