Clinical trial results:
Mesacol: The effect of mesalazine on molecular pathways of cell adhesion in ulcerative colitis

Summary

EudraCT number	2012-002023-15
Trial protocol	AT
Global end of trial date	03 March 2015

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	
Summary attachment (see zip file)	Premature termination of Clinical Trial (Summary Attachment Mesacol.pdf)

Trial information

Trial identification

Sponsor protocol code	Mesacol

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienn, Austria, 1090
Public contact	Medizinische Universität Wien, Medizinische Universität Wien, Universitätsklinik Innere Medizin 3, Abteilung für Gastroenterologie, 0043 1404004764, christoph.gasche@meduniwien.ac.at
Scientific contact	Medizinische Universität Wien, Medizinische Universität Wien, Universitätsklinik Innere Medizin 3, Abteilung für Gastroenterologie, 0043 1404004764, christoph.gasche@meduniwien.ac.at

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	06 May 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 March 2015
Global end of trial reached?	Yes
Global end of trial date	03 March 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the changes in molecular pathways of cell adhesion
(cellular localization of E-cadherin and ß-catenin) in ulcerative colitis prior to and after treatment with mesalazine (5-ASA)

Protection of trial subjects:

Patients' safety was evaluated clinically at every study visit

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2012
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	Austria: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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)	3
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First patient enrolled: May 23rd 2013
Last patient enrolled: Feb 18th 2015
Last patient completed study: Mar 3rd 2015
Recruitment discontinued on Feb 1st 2016 due to low recruitment and expiration of study drug

Pre-assignment

Screening details: -

Period 1

Period 1 title	Treatment
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

not applicable

Arms

Arm title	Treatment arm

Arm description:

Mesalazine-teated

Arm type	Experimental
Investigational medicinal product name	Mesalazine
Investigational medicinal product code	
Other name	Mezavant 1200 mg magensaftresistente Retardtabletten
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three unchewed tablets once daily in the morning, before breakfast, for 14 +/- 2 days, starting on the day after the first endoscopic procedure and continuing until the day before the second endoscopic procedure.

Number of subjects in period 1	Treatment arm
Started	3
Completed	3

Period 2

Period 2 title	Baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Treatment arm

Arm description:

Mesalazine-teated

Arm type	Experimental
Investigational medicinal product name	Mesalazine
Investigational medicinal product code	
Other name	Mezavant 1200 mg magensaftresistente Retardtabletten
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three unchewed tablets once daily in the morning, before breakfast, for 14 +/- 2 days, starting on the day after the first endoscopic procedure and continuing until the day before the second endoscopic procedure.

Number of subjects in period 2	Treatment arm
Started	3
Completed	3

Baseline characteristics

Reporting groups

Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	3	3	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	3	3	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	39		
full range (min-max)	28 to 49	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	2	2	
Endoscopic Mayo score Units: not applicable			
arithmetic mean	2		
full range (min-max)	2 to 2	-	

End points

End points reporting groups

Reporting group title	Treatment arm
Reporting group description: Mesalazine-teated	
Reporting group title	Treatment arm
Reporting group description: Mesalazine-teated	

Primary: Delta-E-cadherin inflamed

End point title	Delta-E-cadherin inflamed
End point description: difference between post-treatment and pre-treatment membranous expression of E-cadherin in inflamed mucosa, evaluated by the immunoreactivity score (IRS) ranging from 0 (no staining) to 4 (strongest staining)	
End point type	Primary
End point timeframe: baseline to post-treatment	

End point values	Treatment arm			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: immunoreactivity score				
arithmetic mean (full range (min-max))	1.3 (0.5 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Delta-beta catenin inflamed

End point title	Delta-beta catenin inflamed
End point description: Change in the immune reactivity score of membranous ß-catenin in inflamed mucosa before and after 5-ASA treatment	
End point type	Secondary
End point timeframe: baseline-end of treatment	

End point values	Treatment arm			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: IRS				
arithmetic mean (full range (min-max))	1.3 (0 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Delta-Mayo

End point title	Delta-Mayo

End point description:

Change in Mayo-Score (endoscopic ulcerative colitis activity score) from baseline to study end

End point type	Secondary

End point timeframe:

baseline-end of treatment

End point values	Treatment arm			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Mayo Score				
arithmetic mean (full range (min-max))	-1.3 (-2 to -1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

baseline-end of study

Assessment type	Non-systematic

Dictionary used

Dictionary name	non used
Dictionary version	0

Reporting groups

Reporting group title	Safety set

Reporting group description:

all patients who received at least one dose of the study drug

Serious adverse events	Safety set		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Safety set		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Study discontinued on Feb 1st 2016 due to low recruitment and expiration of study drug. Because of the insufficient sample size, results were reported only descriptively.

Notes: