



Clinical trial results: The intestinal disposition of sulindac in healthy volunteers Summary

EudraCT number	2019-001496-36
Trial protocol	BE
Global end of trial date	17 November 2019

Results information

Result version number	v1 (current)
This version publication date	01 April 2023
First version publication date	01 April 2023

Trial information

Trial identification

Sponsor protocol code	DDD19CRCSUL
-----------------------	-------------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	Herestraat, Leuven, Belgium, 3000
Public contact	Drug Delivery & Disposition, KU Leuven, glenn.lemmens@kuleuven.be
Scientific contact	Drug Delivery & Disposition, KU Leuven, glenn.lemmens@kuleuven.be

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	20 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the disposition and bioavailability of Arthrocline at the level of the colon and blood respectively

Protection of trial subjects:

Only healthy volunteers could participate in this study protocol

All colonoscopies were performed by a single experienced endoscopist.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 August 2019
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: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Main exclusion criteria:

hepatitis B/C and/or HIV infection

Illness at the time of the study,

allergy for sulindac or NSAIDs in general,

medication use (excluding contraceptives)

a history of acute/chronic gastrointestinal disease(s)

(possible) pregnancy

Pre-assignment

Screening details:

Healthy volunteers

Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	200 mg sulindac
-----------	-----------------

Arm description:

Upon arrival at the endoscopy unit, the volunteers were positioned on their left side and an enema (250 mL of tap water) was administered rectally to rinse the left hemicolon while retaining the physiological state of the right hemicolon.

A colonoscopy was then performed by a single experienced endoscopist to obtain two blank biopsies.

Next, an Arthroline tablet (200 mg sulindac) was orally administered with 240 mL of tap water. The colonoscopy was left untouched. Between 1 and 2.5 h after drug intake, two caecal biopsies were taken every 15 min with a standard biopsy forceps.

After 2.5 h, colonic contents (± 2 mL) were sampled through the suction channel of the colonoscopy and the colonoscopy was retracted.

3 hours later, the colonoscopy was positioned again in order to sample caecal biopsies every 15 min between 6 and 7.5 h after drug intake.

After 7.5 h, colonic contents were collected and colonoscopy was retracted.

Arm type	Experimental
Investigational medicinal product name	sulindac 200 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One arthroline tablet (200 mg sulindac) was orally administered with 240 mL of tap water to the volunteers.

Number of subjects in period 1	200 mg sulindac
Started	6
Completed	5
Not completed	1
failed measurement	1

Baseline characteristics

Reporting groups

Reporting group title	overall study
-----------------------	---------------

Reporting group description: -

Reporting group values	overall study	Total	
Number of subjects	6	6	
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)	6	6	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	3	3	
not recorded	1	1	

Subject analysis sets

Subject analysis set title	successful measurements
----------------------------	-------------------------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

The measurement of 1 healthy volunteer failed. The data of only 5 volunteers could be analyzed.

Reporting group values	successful measurements		
Number of subjects	5		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	5		
From 65-84 years	0		
85 years and over	0		

Gender categorical			
Units: Subjects			
Female	2		
Male	3		
not recorded	0		

End points

End points reporting groups

Reporting group title	200 mg sulindac
-----------------------	-----------------

Reporting group description:

Upon arrival at the endoscopy unit, the volunteers were positioned on their left side and an enema (250 mL of tap water) was administered rectally to rinse the left hemicolon while retaining the physiological state of the right hemicolon.

A colonoscopy was then performed by a single experienced endoscopist to obtain two blank biopsies. Next, an Arthroline tablet (200 mg sulindac) was orally administered with 240 mL of tap water. The colonoscopy was left untouched. Between 1 and 2.5 h after drug intake, two caecal biopsies were taken every 15 min with a standard biopsy forceps.

After 2.5 h, colonic contents (± 2 mL) were sampled through the suction channel of the colonoscopy and the colonoscopy was retracted.

3 hours later, the colonoscopy was positioned again in order to sample caecal biopsies every 15 min between 6 and 7.5 h after drug intake.

After 7.5 h, colonic contents were collected and colonoscopy was retracted.

Subject analysis set title	successful measurements
----------------------------	-------------------------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

The measurement of 1 healthy volunteer failed. The data of only 5 volunteers could be analyzed.

Primary: not applicable

End point title	not applicable ^[1]
-----------------	-------------------------------

End point description:

Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

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

End point timeframe:

not applicable

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: Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

End point values	200 mg sulindac	successful measurements		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5 ^[2]	5		
Units: not applicable	5	5		

Notes:

[2] - 1 measurement failed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

For each individual, corresponds to timeframe of study participation (from signing of informed consent until last visit).

Assessment type	Non-systematic
-----------------	----------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

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

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: there were no adverse events during the trial

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.

Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33002468>