Clinical trial results:
Colchicine twice a day for hand osteoarthritis (COLOR): a double-blind, randomised, placebo-controlled trial

Summary

EudraCT number	2020-002803-20
Trial protocol	DK
Global end of trial date	27 February 2023

Results information

Result version number	v1 (current)
This version publication date	12 July 2023
First version publication date	12 July 2023
Summary attachment (see zip file)	Accepted manuscript (Manuscript_for_sharing_2023.06.20.pdf)

Trial information

Trial identification

Sponsor protocol code	APPI2-2020-AD03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04601883
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	The Parker Institute
Sponsor organisation address	Nordre Fasanvej 57, vej 8, indgang 19, Frederiksberg, Denmark, 2000
Public contact	Osteoarthritis Outpatient Clinic, Parker Instituttet, 45 38164158, henning.bliddal@regionh.dk
Scientific contact	Osteoarthritis Outpatient Clinic, Parker Instituttet, 45 38164158, henning.bliddal@regionh.dk

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 October 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 October 2022
Global end of trial reached?	Yes
Global end of trial date	27 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the effect of oral colchicine 0.5 mg bid, relative to placebo, on changes in finger joint pain of the target hand measured on a visual analogue scale (VAS) from baseline to week 12, in patients with painful hand OA.

Protection of trial subjects:

The study was approved by the Danish Health Research Ethics Committees

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 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)	21
From 65 to 84 years	76
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

For inclusion, people were required to have finger pain at rest of at least 40 mm on a 100-mm visual analogue scale (VAS).

Period 1

Period 1 title	Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Colchicne

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Colchicine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

0,5 mg twice a day (morning and evening) for 12 weeks

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use

Dosage and administration details:

0,5 mg twice a day (morning and evening) for 12 weeks

Number of subjects in period 1	Colchicne	Placebo
Started	50	50
Completed	50	50

Baseline characteristics

Reporting groups	
Reporting group title	Colchicne
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Colchicne	Placebo	Total
Number of subjects	50	50	100
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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	70.2	70.6	
standard deviation	± 7.5	± 7.6	-
Gender categorical Units: Subjects			
Female	34	35	69
Male	16	15	31

Subject analysis sets	
Subject analysis set title	ITT
Subject analysis set type	Full analysis
Subject analysis set description: All randomised participants	

Reporting group values	ITT		
Number of subjects	100		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years)			

Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years arithmetic mean standard deviation	 70.9 ± 7.5		
Gender categorical Units: Subjects			
Female Male	69 31		

End points

End points reporting groups

Reporting group title	Colchicne
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	ITT
Subject analysis set type	Full analysis
Subject analysis set description: All randomised participants	

Primary: Change from baseline in VAS finger pain target hand

End point title	Change from baseline in VAS finger pain target hand
End point description:	
End point type	Primary
End point timeframe: 12 weeks	

End point values	Colchicne	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: milimeter				
least squares mean (standard error)	-13.9 (± 2.8)	-13.5 (± 2.8)		

Statistical analyses

Statistical analysis title	Repeated mixed measures
Comparison groups	Colchicne v Placebo
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9
Method	ANCOVA

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 16 weeks	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0
Reporting groups	
Reporting group title	Colchicine
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Colchicine	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Migraine with aura			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Colchicine	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 50 (72.00%)	22 / 50 (44.00%)	
Cardiac disorders			
Cardiac disorder			
subjects affected / exposed	2 / 50 (4.00%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Nervous system disorders			
Neurological symptom			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
Dizziness			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
General symptom			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Tooth disorder			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Thirst			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Cataract			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Dry skin			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			

White blood cell count abnormal			
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
Thrombophlebitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	24 / 50 (48.00%)	14 / 50 (28.00%)	
occurrences (all)	24	14	
Tearfulness			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Alanine aminotransferase increased			
subjects affected / exposed	10 / 50 (20.00%)	1 / 50 (2.00%)	
occurrences (all)	10	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Urogenital disorder			
subjects affected / exposed	3 / 50 (6.00%)	0 / 50 (0.00%)	
occurrences (all)	0	0	
Glomerular filtration rate increased			
subjects affected / exposed	2 / 50 (4.00%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
Musculoskeletal and connective tissue disorders			
Musculoskeletal disorder			
subjects affected / exposed	8 / 50 (16.00%)	8 / 50 (16.00%)	
occurrences (all)	5	5	
Infections and infestations			
Infection			
subjects affected / exposed	8 / 50 (16.00%)	6 / 50 (12.00%)	
occurrences (all)	8	6	
Metabolism and nutrition disorders			

Bone metabolism disorder subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	2 / 50 (4.00%) 2	
Muscle enzyme increased subjects affected / exposed occurrences (all)	8 / 50 (16.00%) 8	2 / 50 (4.00%) 2	

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

None reported