Clinical trial results:
Eficacia de la colchicina administrada en el primer brote de pericarditis para evitar la aparición de recidivas.

Summary

EudraCT number	2009-011258-16
Trial protocol	ES
Global end of trial date	31 December 2013

Results information

Result version number	v1 (current)
This version publication date	19 December 2021
First version publication date	19 December 2021

Trial information

Trial identification

Sponsor protocol code	COLCHICINE

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org
Scientific contact	Jaime Sagristà/Antonia Sambola, VHIR, asambola@vhebron.net

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	31 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study if administration of colchicine in the first episode of acute idiopathic pericarditis (AIP) is efficient to prevent recurrent episodes
Estudiar si la colchicina administrada en el primer brote de una pericarditis aguda idiopática es eficaz para prevenir la aparición de recidivas.

Protection of trial subjects:

Each visit was performed through a structured interview (questionnaire) where the occurrence of symptoms or signs of a possible new episode of pericarditis were recorded. During follow-up, testing of each visit included basic vital signs and a general physical examination.
All patients received a proton pump inhibitor as gastroduodenal prophylaxis

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2004
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	Spain: 110
Worldwide total number of subjects	110
EEA total number of subjects	110

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)	110
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from February 2004 to May 2010 in 3 Spanish tertiary hospitals

Pre-assignment

Screening details:

The inclusion criteria were: a) AIP evident at the time of inclusion, and b) agreement to participate in the study with provision of informed consent.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Colchicine

Arm description:

Conventional anti-inflammnatory tretament (Aspirin and/or Ibuprofen) plus colchicine

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

Dosage and administration details:

Colchicine orally 1 mg/12 h for patients who weighed more than 70 kg, or 0.5 mg/12h in patients with a weight <70kg, for 3 months

Investigational medicinal product name	Aspirine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Aspirine 1g every 6 or 8 hours, for 2 to 10 days with tapering over 3 to 4 weeks

Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ibuprofen orally 600 mg every 8hours, for 2 to 10 days with tapering over 3 to 4 weeks

Investigational medicinal product name	Indomethacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Indomethacin orally 50mg every 8hours for 2 to 10 days with tapering over 3 to 4 weeks

Arm title	Conventional treatment
Arm description:	
Conventional tertament of aspirin and NSAIDs	
Arm type	Active comparator
Investigational medicinal product name	Aspirine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Aspirine 1g every 6 or 8 hours, for 2 to 10 days with tapering over 3 to 4 weeks	
Investigational medicinal product name	Ibuprofen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Ibuprofen orally 600 mg every 8hours, for 2 to 10 days with tapering over 3 to 4 weeks	
Investigational medicinal product name	Indomethacin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Indomethacin orally 50mg every 8hours for 2 to 10 days with tapering over 3 to 4 weeks	

Number of subjects in period 1	Colchicine	Conventional treatment
Started	59	51
Completed	57	45
Not completed	2	6
Adverse event, serious fatal	1	2
Lost to follow-up	1	4

Baseline characteristics

End points

End points reporting groups

Reporting group title	Colchicine
Reporting group description: Conventional anti-inflammnatory tretament (Aspirin and/or Ibuprofen) plus colchicine	
Reporting group title	Conventional treatment
Reporting group description: Conventional tertament of aspirin and NSAIDs	

Primary: Appearance of recurrent episodes

End point title	Appearance of recurrent episodes
End point description:	
End point type	Primary
End point timeframe: 24 months of follow-up	

End point values	Colchicine	Conventional treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	45		
Units: percent				
number (not applicable)	13.5	7.8		

Statistical analyses

Statistical analysis title	Recurrent pericarditis
Comparison groups	Colchicine v Conventional treatment
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.34
Method	t-test, 2-sided

Secondary: Time to first recurrence

End point title	Time to first recurrence
End point description:	
End point type	Secondary

End point timeframe:
24 months of follow-up

End point values	Colchicine	Conventional treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	51		
Units: month				
arithmetic mean (standard deviation)	9.6 (± 9.0)	8.3 (± 10.5)		

Statistical analyses

Statistical analysis title	Time to first recurrence
Comparison groups	Colchicine v Conventional treatment
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.8
Method	t-test, 2-sided

Secondary: Episode duration

End point title	Episode duration

End point description:

End point type	Secondary

End point timeframe:
24 months of follow-up

End point values	Colchicine	Conventional treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	51		
Units: day				
arithmetic mean (standard deviation)	6.3 (± 2.9)	9.1 (± 3.4)		

Statistical analyses

Statistical analysis title	Episode duration
Comparison groups	Colchicine v Conventional treatment

Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.4
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 24 months follow-up	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1
Reporting groups	
Reporting group title	Colchicine
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Serious adverse events	Colchicine	Control	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 59 (0.00%)	0 / 51 (0.00%)	
number of deaths (all causes)	1	2	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Colchicine	Control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 59 (13.56%)	4 / 51 (7.84%)	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	8 / 59 (13.56%)	0 / 51 (0.00%)	
occurrences (all)	8	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 59 (0.00%)	4 / 51 (7.84%)	
occurrences (all)	0	4	

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.

We only included patients with acute idiopathic/viral pericarditis. Patients with postcardiac injury pericarditis or pericarditis secondary to connective tissue disease were not included. Higher doses of colchicine were used than in previous trials

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30683494