Clinical trial results:
COLIN
Intérêt de la COLchicine dans la prise en charge de l'INfarctus aigu du myocarde avec activité inflammatoire importante.
-Etude pilote

Summary

EudraCT number	2014-002739-32
Trial protocol	FR
Global end of trial date	05 August 2016

Results information

Result version number	v1 (current)
This version publication date	29 June 2022
First version publication date	29 June 2022
Summary attachment (see zip file)	Princeps article (Akodad et al-2017.pdf)

Trial information

Trial identification

Sponsor protocol code	UF9439

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02363725
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UH of Montpellier
Sponsor organisation address	Avenue du Doyen Gaston Giraud, Montpellier, France,
Public contact	Anne VERCHERE, Direction de la Recherche et de l'Innovation, 00 33467330812, depotac@chu-montpellier.fr
Scientific contact	Anne VERCHERE, Direction de la Recherche et de l'Innovation, 00 33467330812, depotac@chu-montpellier.fr

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	04 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 May 2016
Global end of trial reached?	Yes
Global end of trial date	05 August 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Etudier l'impact de la colchicine prise en complément du traitement conventionnel dans la réduction de l'inflammation lors de la prise en charge hospitalière (jusqu'à 7 jours) de l'infarctus du myocarde par rapport au traitement conventionnel seul.
La réduction de l'inflammation sera évaluée par la cinétique de la CRP entre J0 et la sortie d'hospitalisation (J5 à J7).

Protection of trial subjects:

Patients were followed-up by investigator and had investigator contact in case of emergency.
Colchicine dose adaptation were described in the protocol in case of poor tolerance.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2014
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	France: 44
Worldwide total number of subjects	44
EEA total number of subjects	44

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)	29
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All patients admitted for ST-elevationmyocardial infarction (STEMI), with occlusion of one of themain coronary arteries (thrombolysis in myocardial infarc-tion [TIMI] grade 0 or 1 flow), and successfully treatedwith primary percutaneous coronary intervention (PCI),were considered fo

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Conventional treatment

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Colchicine

Arm description: -

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 1 mg per day for 1 month

Number of subjects in period 1	Conventional treatment	Colchicine
Started	21	23
Completed	21	23

Baseline characteristics

Reporting groups	
Reporting group title	Conventional treatment
Reporting group description: -	
Reporting group title	Colchicine
Reporting group description: -	

Reporting group values	Conventional treatment	Colchicine	Total
Number of subjects	21	23	44
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	15	29
From 65-84 years	7	8	15
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	5	4	9
Male	16	19	35

End points

End points reporting groups	
Reporting group title	Conventional treatment
Reporting group description: -	
Reporting group title	Colchicine
Reporting group description: -	

Primary: CRP peak	
End point title	CRP peak
End point description:	
End point type	Primary
End point timeframe: between inclusion and 5 days	

End point values	Conventional treatment	Colchicine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	23		
Units: mg/L				
arithmetic mean (standard deviation)	21.86 (± 25.39)	29.03 (± 25.56)		

Statistical analyses

Statistical analysis title	aA
Comparison groups	Conventional treatment v Colchicine
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.79
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.24
upper limit	17.24
Variability estimate	Standard error of the mean
Dispersion value	5.08

Adverse events

Adverse events information

Timeframe for reporting adverse events:

upon knowledge of the adverse event

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	ALL PATIENTS

Reporting group description: -

Serious adverse events	ALL PATIENTS		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 44 (34.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
coronarography			
subjects affected / exposed	4 / 44 (9.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Epidermoid carcinoma			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
crescendo angina			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

decompensation cardiac				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Left ventricular dysfunction				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ventricular fibrillation				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Angioplasty				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Double vessel bypass graft				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
implatable defibrillator insertion				
subjects affected / exposed	4 / 44 (9.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
implantable defibrillator removal				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatrist consultation				
subjects affected / exposed	1 / 44 (2.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radiotherapy				

subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	5 / 44 (11.36%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
implantable cardiac defibrillator infection			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	ALL PATIENTS		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 44 (70.45%)		
Injury, poisoning and procedural complications			
bruising of arm			
subjects affected / exposed	2 / 44 (4.55%)		
occurrences (all)	2		
Vascular disorders			
thrombus			
subjects affected / exposed	3 / 44 (6.82%)		
occurrences (all)	3		
Cardiac disorders			

Pericardial disease subjects affected / exposed occurrences (all) Pericardial effusion subjects affected / exposed occurrences (all)	4 / 44 (9.09%) 4 2 / 44 (4.55%) 2		
Surgical and medical procedures Therapy cessation subjects affected / exposed occurrences (all)	4 / 44 (9.09%) 4		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 44 (4.55%) 2		
General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Unevaluable event subjects affected / exposed occurrences (all)	5 / 44 (11.36%) 3 2 / 44 (4.55%) 2 2 / 44 (4.55%) 2		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	9 / 44 (20.45%) 9 3 / 44 (6.82%) 3		
Musculoskeletal and connective tissue disorders painful arm subjects affected / exposed occurrences (all)	2 / 44 (4.55%) 2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2014	Identification of DSMB members
05 January 2015	Modification of premature end of trial; Modification of patients follow-up; Modification of labels of experimental treatment
22 June 2015	Modification of DSMB members
13 May 2016	Additionnal blood analysis added for all patients included

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28065445