



Clinical trial results: EFFECT OF THE ADMINISTRATION OF ALLOPURINOL ON THE PREVENTION OF MUSCLE MASS LOSS IN IMMOBILIZED SUBJECTS.

Summary

EudraCT number	2011-003541-17
Trial protocol	ES
Global end of trial date	31 August 2015

Results information

Result version number	v1 (current)
This version publication date	12 February 2022
First version publication date	12 February 2022

Trial information

Trial identification

Sponsor protocol code	ALMU_2011
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Instituto de Investigación Sanitaria La Fe de Valencia
Sponsor organisation address	Avenida Fernando Abril Martorell, Torre 106 A 7planta, 46026 València, , Valencia, Spain,
Public contact	UREC, Instituto de Investigacion Sanitaria La Fe, 34 963862758, investigacion_clinica@iislafe.es
Scientific contact	UREC, Instituto de Investigacion Sanitaria La Fe, 34 963862758, investigacion_clinica@iislafe.es

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	30 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 July 2015
Global end of trial reached?	Yes
Global end of trial date	31 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determining the effect of allopurinol administration on the prevention of loss of muscle mass in immobilized subjects. In this way we aim to determine the role of xanthine oxidase in free radical production in skeletal muscle during a period of immobilization

Protection of trial subjects:

The reference study was conducted in Spain under the legal framework of Royal Decree 1090/2015. It has been performed in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996). In addition, the study has been conducted in accordance with the protocol, good clinical practice (GCP) in accordance with the guidelines of the international conference on harmonization (ICH) and regulatory requirements for participating institutions.

An appropriately performed informed consent has been used, in compliance with GCP according to ICH guidelines and approved by the CEIm of the Hospital Universitario y Politécnico La Fe. Prior to inclusion of subjects in the study, a copy of the CEIm-approved informed consent has been reviewed with the prospective participant, signed and dated. The investigator has provided a copy of each subject's signed informed consent form and has retained a copy in the subject's study file.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 November 2011
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: 53
Worldwide total number of subjects	53
EEA total number of subjects	53

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)	53
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The patient inclusion period is estimated at 1 year from the start of the study. Hospital Universitari i Politècnic La Fe Valencia.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	53
Number of subjects completed	

Period 1

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

Blinding implementation details:

N/A

Arms

Are arms mutually exclusive?	Yes
Arm title	Patients with grade II ankle sprain Alopurinol

Arm description:

Patients with grade II ankle sprain

Arm type	Active comparator
Investigational medicinal product name	ALOPURINOL
Investigational medicinal product code	M04AA01
Other name	
Pharmaceutical forms	Buccal tablet
Routes of administration	Buccal use

Dosage and administration details:

Allopurinol 300 mg / 24 hours orally.

Therapeutic group: M04AA01

Administration way: Oral

Dose: 300 mg / 24h

Arm title	Patients with grade II ankle sprain Non Alopurinol
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Arm description:

Patients with grade II ankle sprain

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Health patient with Alopurinol
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Arm description:

Health patient

Arm type	Active comparator
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Investigational medicinal product name	ALOPURINOL
Investigational medicinal product code	M04AA01
Other name	
Pharmaceutical forms	Buccal tablet
Routes of administration	Buccal use
Dosage and administration details: Allopurinol 300 mg / 24 hours orally. Therapeutic group: M04AA01 Administration way: Oral Dose: 300 mg / 24h	
Arm title	Health patient Non Alopurinol
Arm description: Health patient	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Patients with grade II ankle sprain Alopurinol	Patients with grade II ankle sprain Non Alopurinol	Health patient with Alopurinol
Started	18	17	5
Completed	13	12	4
Not completed	5	5	1
Lost to follow-up	5	5	1

Number of subjects in period 1	Health patient Non Alopurinol
Started	13
Completed	13
Not completed	0
Lost to follow-up	-

Baseline characteristics

Reporting groups

Reporting group title	Patients with grade II ankle sprain Alopurinol
Reporting group description:	
Patients with grade II ankle sprain	
Reporting group title	Patients with grade II ankle sprain Non Alopurinol
Reporting group description:	
Patients with grade II ankle sprain	
Reporting group title	Health patient with Alopurinol
Reporting group description:	
Health patient	
Reporting group title	Health patient Non Alopurinol
Reporting group description:	
Health patient	

Reporting group values	Patients with grade II ankle sprain Alopurinol	Patients with grade II ankle sprain Non Alopurinol	Health patient with Alopurinol
Number of subjects	18	17	5
Age categorical			
Range of age between 18-40 years			
Units: Subjects			
Adults 18 - 40 years	13	12	4
Not Recorded	5	5	1
Gender categorical			
Units: Subjects			
Male	13	12	4
Not recorded	5	5	1

Reporting group values	Health patient Non Alopurinol	Total	
Number of subjects	13	53	
Age categorical			
Range of age between 18-40 years			
Units: Subjects			
Adults 18 - 40 years	13	42	
Not Recorded	0	11	
Gender categorical			
Units: Subjects			
Male	13	42	
Not recorded	0	11	

End points

End points reporting groups

Reporting group title	Patients with grade II ankle sprain Alopurinol
Reporting group description: Patients with grade II ankle sprain	
Reporting group title	Patients with grade II ankle sprain Non Alopurinol
Reporting group description: Patients with grade II ankle sprain	
Reporting group title	Health patient with Alopurinol
Reporting group description: Health patient	
Reporting group title	Health patient Non Alopurinol
Reporting group description: Health patient	

Primary: percentage of muscle loss

End point title	percentage of muscle loss
End point description:	
End point type	Primary
End point timeframe: Treatment will be administered during the 15-day immobilization period and medication will be discontinued.	

End point values	Patients with grade II ankle sprain Alopurinol	Patients with grade II ankle sprain Non Alopurinol	Health patient with Alopurinol	Health patient Non Alopurinol
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	12	4	13
Units: Change of volume				
number (not applicable)	13	12	4	13

Statistical analyses

Statistical analysis title	Control vs allopurinol
Statistical analysis description: All the results will be expressed as mean values \pm standard deviation, indicating the number of observations in parentheses. The statistical treatment of the results obtained, when comparing control groups with groups treated with allopurinol, is performed using Student's t-test. Knowing the t value and the degrees of freedom, the value of the probability "p" that the differences between the measurements of two sets of values is statistically significant is accepted to be less than 0.05 or 0.01.	
Comparison groups	Patients with grade II ankle sprain Non Alopurinol v Patients with grade II ankle sprain Alopurinol v Health patient with

	Alopurinol v Health patient Non Alopurinol
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	< 0.01
Method	t-test, 2-sided
Parameter estimate	Median difference (final values)
Point estimate	8.2
Confidence interval	
level	95 %
sides	1-sided
lower limit	0
Variability estimate	Standard deviation

Notes:

[1] - Quantification of the changes in soleus muscle CSA during lower leg immobilization with a posterior ankle splint

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The investigator will report all SAEs immediately (within 24 hours) after becoming aware of the event. The report has to be communicated to the promoter. The initial report will be immediately followed by detailed written reports and reflected in the CRF.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

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: For this study, given its low level of risk, no adverse events have occurred.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 June 2015	protocol changes

Notes:

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.

N/A

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29476130>