Clinical trial results:
JAB02 Repurposing allopurinol as a novel anti-inflammatory treatment for persistent allergic asthma.

Summary

EudraCT number	2016-000164-42
Trial protocol	GB
Global end of trial date	03 October 2017

Results information

Result version number	v1 (current)
This version publication date	28 December 2019
First version publication date	28 December 2019
Summary attachment (see zip file)	EudraCT Results Report - JAB02 (Summary of Research Report - 16-ES-0037 - 2016-000164-42.pdf)

Trial information

Trial identification

Sponsor protocol code	2016RC01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Dundee - NHS Tayside
Sponsor organisation address	Residency Block, Level 3, Ninewells Hospital, George Pirie Way, Dundee, United Kingdom, DD1 9SY
Public contact	Professor Brian Lipworth, Scottish Centre for Respiratory Research, 44 01382 383188 , b.j.lipworth@dundee.ac.uk
Scientific contact	Professor Brian Lipworth, Scottish Centre for Respiratory Research, 44 01382 383188 , b.j.lipworth@dundee.ac.uk

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	03 October 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 October 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Does allopurinol confer any anti-inflammatory benefit to the airways of patients with asthma? In specific, does it reduce airway hyperresponsiveness (a marker of disease activity). This will be measured by challenging the airways with a drug designed to provoke bronchoconstriction.

We hypothesise that patients on allopurinol will be less reactive to the bronchial challenge. Thereby demonstrating it has tangible anti-inflammatory properties to the airways of asthmatic patients.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2017
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	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is a "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Allopurinol
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Allopurinol 300 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Dosage would have been 300 mg once daily

Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Dosage would have been 1 placebo capsule once daily.

Number of subjects in period 1	Allopurinol	Placebo
Started	99999	99999
Completed	99999	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	99999	99999	
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)	0	0	
From 65-84 years	99999	99999	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Allopurinol
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Mannitol PD15

End point title	Mannitol PD15[1]

End point description:

99999 is a "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the trial.

End point type	Primary

End point timeframe:

N/a

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: No subjects were enrolled in the trial, therefore there are no results available.

End point values	Allopurinol	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: mg				
log mean (standard deviation)	()	()		

Notes:

[2] - No subjects were enrolled in the trial, therefore there are no results available.

[3] - No subjects were enrolled in the trial, therefore there are no results available.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events would have been recorded from the time a participant consented to join the study until their last study visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

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: No subjects were enrolled in the trial, therefore there are no results available.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 August 2017	REC Amendment - Amendment to include requirement for subjects to have Mannitol PD15 </= 635mg at both baselines of the cross-over study.

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.

99999 is a "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the trial.

Notes: