Clinical trial results:
Influence of aromatase inhibitors on insulin sensitivity, liver and hart function in obese men

Summary

EudraCT number	2013-002964-22
Trial protocol	BE
Global end of trial date	15 May 2015

Results information

Result version number	v1 (current)
This version publication date	02 December 2021
First version publication date	02 December 2021
Summary attachment (see zip file)	Statement of discontinuation (2013-002964-22 Statement of discontinuation.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2013/009

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Cormaal Hetmanslaan 10, Ghent, Belgium, 9000
Public contact	HIRUZ CTY, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be

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	15 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2015
Global end of trial reached?	Yes
Global end of trial date	15 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate potential effects and causes of changed sex steroids in obese men

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 July 2014
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	Belgium: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

1 patients were screened in the period from dand included before discontinuation of the trial. End of trial notification was dated 15-Jun-2015 (last patient last visit) and submitted to EC and CA 24-Jun-2015

Pre-assignment

Screening details:

Main inclusion criteria:
Adult obese mails with low testosteron scheduled for gastric bypass

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, Carer, Assessor

Arms

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

Dosage and administration details:

2.5 mg every 2 days during 4 months

Number of subjects in period 1	Letrozole
Started	1
Completed	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Letrozole

Reporting group description: -

Primary: Insulin sensitivity

End point title	Insulin sensitivity[1]

End point description:

End point type	Primary

End point timeframe:

Difference between start of treatment and end of treatment (4 months)

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 analysis done as study has discontinued

End point values	Letrozole			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: mg/dl				
number (not applicable)	1			

Notes:

[2] - Not analysed as study ended prematurly

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Overall study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

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 adverse events were collected during the trial

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