Clinical trial results:
The impact of Rimonabant in overweight women with prior gestational diabetes

Summary

EudraCT number	2007-000907-13
Trial protocol	AT
Global end of trial date	04 November 2008

Results information

Result version number	v1 (current)
This version publication date	06 June 2019
First version publication date	06 June 2019

Trial information

Trial identification

Sponsor protocol code	2007-24-001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Prof. Dr. Alexandra Kautzky-Willer , Department of Medicine III, Devision of Endocrinology and Metabolism, alexandra.kautzy-willer@meduniwien.ac.at
Scientific contact	Prof. Dr. Alexandra Kautzky-Willer , Department of Medicine III, Devision of Endocrinology and Metabolism, alexandra.kautzy-willer@meduniwien.ac.at

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	06 August 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 August 2008
Global end of trial reached?	Yes
Global end of trial date	04 November 2008
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Aim of this study is to test the hypothesis that drug therapy with Rimonabant (20 mg/day) for 6 months in overweight women with prior gestational diabetes and impaired glucose tolerance at the postpartum reclassification will i) improve dyslipidemia, insulin sensitivity, beta cell-function and ii) reduce abdominal obesity or body weight and thus iii) convert glucose tolerance or iiii) reduce risk for progression to diabetes and iiiii) will also improve the cardiovascular risk profile compared to age and BMI matched women with prior gestational diabetes but without drug therapy.

Protection of trial subjects:

Laboratory assessments at the beginning of the study and three and six months after initiation.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2007
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	Austria: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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)	4
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

30 women will be recruited from the outpatient clinic of the Department of Internal Medicine III, Division of Endocrinology and Metabolism, University Clinic of Vienna.

Pre-assignment

Screening details:

Inclusion criteria:
Age: 20-50 years
BMI: >30kg/m2 or 27kg/m2 if additional cardivaskular risk parameters are present:
prediabetes or diabetes, metabolic syndrome (WHO-Criteria), lipids: HDL cholesterol: <50mg/dl or triglycerides >150mg/dl
Exclusion criteria:
kidney or liver disease, any chronic disease, acute or chronic inflammatory disease

Pre-assignment period milestones

Number of subjects started	4
Number of subjects completed	4

Period 1

Period 1 title	Baseline Period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Rimonabant Group

Arm description:

Obese women with insulin resistance and/or prediabetes (IGT/IFG), type 2 diabetes or dyslipidemia who have finished lactation will be assigned to therapy with Rimonabant.

Arm type	Active comparator
Investigational medicinal product name	Rimonabant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

20mg/daily

Number of subjects in period 1	Rimonabant Group
Started	4
Completed	4

Baseline characteristics

Reporting groups	
Reporting group title	Rimonabant Group
Reporting group description:	
Obese women with insulin resistance and/or prediabetes (IGT/IFG), type 2 diabetes or dyslipidemia who have finished lactation will be assigned to therapy with Rimonabant.	

Reporting group values	Rimonabant Group	Total	
Number of subjects	4	4	
Age categorical			
AGE 20-50 years			
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)	4	4	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	0	0	

End points

End points reporting groups

Reporting group title	Rimonabant Group

Reporting group description:

Obese women with insulin resistance and/or prediabetes (IGT/IFG), type 2 diabetes or dyslipidemia who have finished lactation will be assigned to therapy with Rimonabant.

Primary: reduce weight

End point title	reduce weight[1]

End point description:

End point type	Primary

End point timeframe:

baseline - after 3 months - at the end of the study (6 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: Because of the termination at the initial phase of the trial NO evaluation of the results was possible.

End point values	Rimonabant Group			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: kg				

Notes:

[2] - Because of the early termination of the trial NO evaluation of the results was possible.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: SAE reporting: <24 hours non-serious-AE reporting: 5 calendar days	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.1

Frequency threshold for reporting non-serious adverse events: 0 %

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: The study was terminated earlier, because approval of Rimonabant was suspended and the BASG recommended to stop all trials with Rimonabant. During this very short study duration there were NO non-serious adverse events recorded.

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? Yes

Date	Interruption	Restart date
04 November 2008	The study was terminated earlier, because approval of Rimonabant (Acomplia) was suspended and the BASG recommended to stop all trials with Rimonabant.	-

Notes:

Limitations and caveats

None reported