



Clinical trial results:

The role of leptin in regulating hepatic lipid metabolism in humans

Summary

EudraCT number	2017-003014-22
Trial protocol	AT
Global end of trial date	24 November 2024

Results information

Result version number	v1 (current)
This version publication date	25 April 2026
First version publication date	25 April 2026

Trial information

Trial identification

Sponsor protocol code	Thalamus_V3
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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	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Sekretariat Endokrinologie, Medical University of Vienna, 0043 14040043100, peter.wolf@meduniwien.ac.at
Scientific contact	Sekretariat Endokrinologie, Medical University of Vienna, 0043 14040043100, peter.wolf@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	01 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 August 2022
Global end of trial reached?	Yes
Global end of trial date	24 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Define the role of leptin action in regulating hepatic VLDL secretion, lipid content and energy metabolism in healthy human subjects

Protection of trial subjects:

Study days according to standardised operating procedures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2018
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	Austria: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

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)	47
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was done in the outpatient's department via online advertisement

Pre-assignment

Screening details:

Inclusion and exclusion criteria: male, aged between 18 and 70 years with plasma triglycerides below 150 mg/dL at screening. In cohort 3, female liver transplant recipients were also eligible. Further inclusion criteria for cohort 3 were: liver transplantation more than 6 months

Period 1

Period 1 title	Healthy subjects (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Arm title	Metreleptin
Arm description: active substance (metreleptin; 0,1 mg/kg/BW) or placebo as single s.c. injection; cross-over design	
Arm type	Active comparator
Investigational medicinal product name	Metreleptin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosage and administration details:
0,1 mg/kg/BW

Number of subjects in period 1	Metreleptin
Started	47
Completed	42
Not completed	5
Screening failure	1
Adverse event, non-fatal	1
Protocol deviation	2
Hypertriglyceridemia	1

Baseline characteristics

Reporting groups

Reporting group title	Healthy subjects (overall period)
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Reporting group description: -

Reporting group values	Healthy subjects (overall period)	Total	
Number of subjects	47	47	
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)	47	47	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	12	12	
Male	35	35	

Subject analysis sets

Subject analysis set title	Metreleptin
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Subject analysis set type	Per protocol
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Subject analysis set description:

0,1 mg/kg/BW as a single injection (1x)

Subject analysis set title	Placebo
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Subject analysis set type	Per protocol
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Subject analysis set description:

0,9% NaCl (equal volume), s.c. injection

Reporting group values	Metreleptin	Placebo	
Number of subjects	42	42	
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)	42	42	

From 65-84 years	0	0	
85 years and over	0	0	

Gender categorical			
Units: Subjects			
Female	11	11	
Male	31	31	

End points

End points reporting groups

Reporting group title	Metreleptin
Reporting group description: active substance (metreleptin; 0,1 mg/kg/BW) or placebo as single s.c. injection; cross-over design	
Subject analysis set title	Metreleptin
Subject analysis set type	Per protocol
Subject analysis set description: 0,1 mg/kg/BW as a single injection (1x)	
Subject analysis set title	Placebo
Subject analysis set type	Per protocol
Subject analysis set description: 0,9% NaCl (equal volume), s.c. injection	

Primary: VLDL triglyceride secretion rate

End point title	VLDL triglyceride secretion rate
End point description: Intralipid protocol	
End point type	Primary
End point timeframe: measured 1x / treatment arm	

End point values	Metreleptin	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	42		
Units: mg/h				
number (not applicable)	438	329		

Statistical analyses

Statistical analysis title	Paired T-tests
Statistical analysis description: Paired T-tests	
Comparison groups	Metreleptin v Placebo
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Study duration

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Metreleptin + Placebo
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Reporting group description: -

Serious adverse events	Metreleptin + Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 47 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Metreleptin + Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 47 (2.13%)		
Skin and subcutaneous tissue disorders			
mild anaphylactoid reaction to intralipid infusion			
subjects affected / exposed	1 / 47 (2.13%)		
occurrences (all)	1		

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/36220067>

<http://www.ncbi.nlm.nih.gov/pubmed/40204211>