



Clinical trial results:

The effect of corticotropin release hormone on duodenal markers and gastric sensorimotor function in healthy volunteers

Summary

EudraCT number	2021-000594-81
Trial protocol	BE
Global end of trial date	22 June 2023

Results information

Result version number	v1 (current)
This version publication date	20 November 2025
First version publication date	20 November 2025

Trial information

Trial identification

Sponsor protocol code	S65020
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZLeuven KULeuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	TARGID, KU Leuven UZLeuven, jan.tack@kuleuven.be
Scientific contact	TARGID, KU Leuven UZLeuven, jan.tack@kuleuven.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	12 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 June 2023
Global end of trial reached?	Yes
Global end of trial date	22 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part 1

- The effect of corticotrophin release hormone (CRH) on duodenal mast cell count in healthy volunteers

Part 2

- The effect of CRH on sensitivity to gastric distention in healthy volunteers

Protection of trial subjects:

Healthy volunteers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 May 2021
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

healthy volunteers
public advertisement

Pre-assignment

Screening details:

Healthy volunteers (HVs) aged 18–55 yr old
no history of abdominal surgeries
no gastrointestinal symptoms.
no individuals with systemic disease
no medication,
no pregnant or lactating women,
no women contemplating pregnancy

Period 1

Period 1 title	CRH and placebo on gastric function (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Arms

Are arms mutually exclusive?	No
Arm title	CRH infusion

Arm description:

HVs were randomized to receive either peripheral administered human CRH or placebo (0.9%NaCl), After an overnight fast, the HVs underwent a 4-h gastric emptying breath tests, body surface gastric mapping (BSGM) for gastric myoelectrical activity recording with symptomprofiling and, on separate days, a gastric barostat
to assess gastric sensitivity and accommodation during CRH or placebo infusion

Arm type	Experimental
Investigational medicinal product name	CORTICOTROPIN-RELEASING HORMONE
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection/infusion
Routes of administration	Intravenous bolus use , Intravenous use

Dosage and administration details:

100 ug bolus and 1 ug/kg/h continuous infusion CRH (CRH Ferring, Ferring Pharmaceuticals, Germany)

Arm title	placebo infusion
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Arm description:

HVs were randomized to receive either peripheral administered human CRH or placebo (0.9%NaCl), After an overnight fast, the HVs underwent a 4-h gastric emptying breath tests, body surface gastric mapping (BSGM) for gastric myoelectrical activity recording with symptomprofiling and, on separate days, a gastric barostat
to assess gastric sensitivity and accommodation during CRH or placebo infusion

Arm type	Placebo
Investigational medicinal product name	saline (0.9% NaCl, Baxter, Belgium)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use , Intravenous use

Dosage and administration details:

1mL bolus and 0.1mL/kg/h continuous infusion

Number of subjects in period 1	CRH infusion	placebo infusion
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups

Reporting group title	CRH and placebo on gastric function
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Reporting group description: -

Reporting group values	CRH and placebo on gastric function	Total	
Number of subjects	20	20	
Age categorical			
Units: Subjects			
Adults (18-64 years)	20	20	
Age continuous			
20 healthy volunteers			
Units: years			
arithmetic mean	29.2		
standard deviation	± 5.3	-	
Gender categorical			
Units: Subjects			
Female	13	13	
Male	7	7	

End points

End points reporting groups

Reporting group title	CRH infusion
Reporting group description: HVs were randomized to receive either peripheral administered human CRH or placebo (0.9%NaCl), After an overnight fast, the HVs underwent a 4-h gastric emptying breath tests, body surface gastric mapping (BSGM) for gastric myoelectrical activity recording with symptomprofiling and, on separate days, a gastric barostat to assess gastric sensitivity and accommodation during CRH or placebo infusion	
Reporting group title	placebo infusion
Reporting group description: HVs were randomized to receive either peripheral administered human CRH or placebo (0.9%NaCl), After an overnight fast, the HVs underwent a 4-h gastric emptying breath tests, body surface gastric mapping (BSGM) for gastric myoelectrical activity recording with symptomprofiling and, on separate days, a gastric barostat to assess gastric sensitivity and accommodation during CRH or placebo infusion	

Primary: gastric emptying rate

End point title	gastric emptying rate
End point description: Compared with placebo, infusion of CRH significantly decreased the T1/2, compared with placebo (65.2 ± 17.4 vs. 78.8 ± 24.5min, P = 0.02).	
End point type	Primary
End point timeframe: active period (CRH) vs placebo period	

End point values	CRH infusion	placebo infusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: minute				
arithmetic mean (standard deviation)	65.2 (± 17.4)	78.8 (± 24.5)		

Statistical analyses

Statistical analysis title	gastric emptying rate
Comparison groups	CRH infusion v placebo infusion
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.02
Method	t-test, 1-sided
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

For each individual, corresponds to timeframe of study participation (from signing of informed consent until last visit).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23
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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 experienced / registered during this study

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/38375576>