Clinical trial results:
Experiencing the self through touch - self-other-distinction in an altered state of self: An exploratory randomized placebo-controlled experimental medicine study

Summary

EudraCT number	2020-004487-25
Trial protocol	SE
Global end of trial date	25 November 2022

Results information

Result version number	v1 (current)
This version publication date	06 March 2024
First version publication date	06 March 2024

Trial information

Trial identification

Sponsor protocol code	KETASELF-1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Linköpings Universitet
Sponsor organisation address	Linköping Campus US, Linköping, Sweden,
Public contact	Markus Heilig, Linköpings Universitet, 0046 1036479, Markus.Heilig@liu.se
Scientific contact	Markus Heilig, Linköpings Universitet, 0046 1036479, Markus.Heilig@liu.se

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	17 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 November 2022
Global end of trial reached?	Yes
Global end of trial date	25 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. Psychophysical measure: Tactile detection threshold during self-touch will be lower during the ketamine- than during the placebo-session.
2. Neurophysiological measure: The difference between neural signatures of self-touch and other-touch will be smaller during the ketamine session than during the placebo-session.

Protection of trial subjects:

To minimize the risks, only healthy volunteers were included in the study. The research subjects were required not to be pregnant or planning to become pregnant during study participation. For women of childbearing age, the use of a highly effective contraceptive was required throughout the study participation. All female research subjects also underwent pregnancy tests at visits 1, 3, and 4 to minimize the risk of fetal exposure to ketamine.

Ketamine infusion
Individuals with predisposing conditions such as respiratory diseases were excluded. During the MRI sessions when ketamine infusion was given, the participants were carefully monitored by a nurse and via physiological parameters. The study participants had access to an alarm button with which they could signal any problems to the study staff and were then allowed to leave the MR machine. Any adverse events were recorded at visits 3 and 4 and at follow-up telephone calls after both of these visits.

MRI examination
The study participants were provided with earplugs to protect them from the high noise level in the MRI. A research nurse was present at the experiment and provided subjects with detailed MRI safety information before entering the MRI room. The research nurse ensured that the participant did not enter the room with ferromagnetic metal objects on or inside the body.

Intravenous catheterization
The risks of intravenous catheterization were minimized with the help of experienced medical personnel who used sterile technique and took standard precautions.

Integrity
To minimize the risk of breach of privacy, the research subject was assigned a study code, and all samples and collected data were labeled with this code. All data were stored on computers that were password-protected and encrypted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2021
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	Sweden: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	30
Number of subjects completed	30

Period 1

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

Blinding implementation details:

The pharmacy prepared, based on the randomization list, an infusion bag containing ketamine or placebo. Both products looked identical and a blinded label was added on the bag. Randomization and blinding were insulated from any of the investigators and study staff.

Arms

Arm title	ketamine

Arm description:

ketamine-placebo within subject (randomized session order)

Arm type	Experimental
Investigational medicinal product name	Ketamine
Investigational medicinal product code	
Other name	Abcur 10mg/ml
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

0.5 mg*kg bodyweight per 40 min = 0.0125 mg*kg bodyweight per min

Investigational medicinal product name	0.9% NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

0.9% NaCl

Number of subjects in period 1	ketamine
Started	30
Completed	30

Baseline characteristics

Reporting groups	
Reporting group title	main

Reporting group description: -

Reporting group values	main	Total	
Number of subjects	30	30	
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)	30	30	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	15	15	
Male	15	15	

End points

End points reporting groups

Reporting group title	ketamine
Reporting group description: ketamine-placebo within subject (randomized session order)	

Primary: self-other-distinction measures - see article

End point title	self-other-distinction measures - see article[1]
End point description:	
End point type	Primary
End point timeframe: start-end	

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: This is an within-subject repeated measures fMRI analysis, which I am not able to manage to fit into this reporting scheme. The primary endpoint results are reported in the published article.

End point values	ketamine			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: 1	30			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Inclusion - Follow-up phone call 2-3 days after last study visit	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	all subjects

Reporting group description: -

Serious adverse events	all subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	all subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 30 (56.67%)		
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Headache			
alternative assessment type: Systematic			

subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Migraine			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	2		
General disorders and administration site conditions			
Feeling cold			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Discomfort			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastritis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Eye disorders			
Eye pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Vomiting			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Eczema			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Urticaria			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Psychiatric disorders			
Depersonalisation/derealisation disorder			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Insomnia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nightmare			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Infections and infestations			
Cystitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Eye infection			

alternative assessment type: Systematic			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 30 (23.33%)		
occurrences (all)	8		

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