Clinical trial results:
Electroconvulsive therapy vs. esketamine nasal spray in treatment-resistant depression: a longitudinal, randomized efficacy comparison pilot study

Summary

EudraCT number	2020-004172-17
Trial protocol	AT
Global end of trial date	01 June 2022

Results information

Result version number	v1 (current)
This version publication date	29 January 2023
First version publication date	29 January 2023

Trial information

Trial identification

Sponsor protocol code	ETES

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Innsbruck
Sponsor organisation address	Innrain 52, Innsbruck, Austria, 6020
Public contact	Kompetenzzentrum klinische Studien, Medizinische Universität Innsbruck, kks-regulatory@i-med.ac.at
Scientific contact	Kompetenzzentrum klinische Studien, Medizinische Universität Innsbruck, kks-regulatory@i-med.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	25 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 June 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the effectiveness of electroconvulsive therapy (ECT) vs. esketamine nasal spray using the Montgomery Asberg Depression Rating Scale (MADRS)

Protection of trial subjects:

weekly assesment

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 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	Austria: 99999999
Worldwide total number of subjects	99999999
EEA total number of subjects	99999999

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)	99999999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

no patients recruited

Pre-assignment

Screening details:

no patients recruited

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Ketamine
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Spravato
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use
Dosage and administration details: 56 mg (2 devices of SPRAVATO™)	
Arm title	ECT-Arm
Arm description: -	
Arm type	Electroconvulsive Therapy
No investigational medicinal product assigned in this arm	

Number of subjects in period 1[1]	Ketamine	ECT-Arm
Started	99999	99999
Completed	99999	99999

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: we did not enroll any patients.

Baseline characteristics

End points

End points reporting groups

Reporting group title	Ketamine
Reporting group description: -	
Reporting group title	ECT-Arm
Reporting group description: -	

Primary: effect of treatment (ECT vs. esketamine) on depression MADRS

End point title	effect of treatment (ECT vs. esketamine) on depression

End point description:

End point type	Primary

End point timeframe:

non, because no patients recruited

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: we did not recruit any patients. Therefor we have no statistical analysis

End point values	Ketamine	ECT-Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: 60				

Notes:

[2] - no patients recruited, study suspended

[3] - no patients recruited

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: n.a.	
Assessment type	Systematic

Dictionary used	
Dictionary name	n.a.
Dictionary version	n.a.

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: we did not recruit any patients. Therefor we have no non-serious adverse events

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