Clinical trial results:
A randomised feasibility trial investigating Sativex® for the treatment of the Agitation & Aggression (A/A) in Alzheimer's Dementia.

Summary

EudraCT number	2020-001056-17
Trial protocol	GB
Global end of trial date	23 August 2023

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025
Summary attachment (see zip file)	STAND CSR 17Jul24 (STAND Trial Clinical Study Report_V.1 17Jul24_FINAL.pdf)

Trial information

Trial identification

Sponsor protocol code	3606

Additional study identifiers

ISRCTN number	ISRCTN97163562
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Kings College London
Sponsor organisation address	KHPCTO F16, Guys Hospital, London, United Kingdom, SE1 9RT
Public contact	Chris Albertyn, Kings College London, +44 02078480548, chris.albertyn@kcl.ac.uk
Scientific contact	Chris Albertyn, Kings College London, +44 02078480548, chris.albertyn@kcl.ac.uk
Sponsor organisation name	South London & Maudsley NHS Foundation Trust
Sponsor organisation address	KHPCTO F16, Guys Hospital, London, United Kingdom, SE5 8AB
Public contact	Dag Aarsland , IoPPN, King's College London, 16 De Crespigny Park, Camberwell, +44 2078480626, dag.aarsland@kcl.ac.uk
Scientific contact	Dag Aarsland, IoPPN, King's College London, 16 De Crespigny Park, Camberwell, +44 2078480496, dag.aarsland@kcl.ac.uk

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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 August 2022
Global end of trial reached?	Yes
Global end of trial date	23 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Feasibility:
To employ a mixed methods approach to explore the feasibility of a definitive multicentre randomized controlled trial (RCT) within residential nursing home settings of Sativex® for treatment of agitation and aggression in AD. Further, our primary objectives will be;

1. To explore rate of recruitment and retention in the target population, including determining facilitators and barriers.

2. To determine whether the cut-off of 'clinically significant' agitation for CMAI or NPI-NH influences rate of recruitment fora future confirmatory trial

3. To investigate the acceptability of an oral mucosal method of administration for this indication in terms of compliance and to care home staff in terms of adherence to the titration schedule.

4. To investigate the acceptability of a cannabinoid-based medicine, and explore impact of societal attitudes and stigma within this patient population as part of the qualitative evaluation.

Protection of trial subjects:

Participants have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw patients from the study drug in the event of inter-current illness, AEs, SAE's, SUSAR's, protocol violations, administrative reasons or other reasons. It is understood by all concerned that an excessive rate of withdrawals can render the study un-interpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient wish to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible, and to keep them for future outcome data collection. Upon confirming formal withdrawal, administration of Sativex® or placebo will immediately cease; STAND researchers will collect remaining supply from the care home and return to the pharmacy for destruction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 November 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	United Kingdom: 29

Worldwide total number of subjects	29
EEA total number of subjects	0

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)	2
From 65 to 84 years	16
85 years and over	11

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	53[1]
Number of subjects completed	29

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screen Failures: 24

Notes:

[1] - The number of subjects reported to have started the pre-assignment 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 do not count screening participants as enrolled

Period 1

Period 1 title	Overall Trial
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Carer, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Sativex

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sativex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal spray
Routes of administration	Oromucosal use

Dosage and administration details:

Dosing will be determined by number of sprays per day. Each spray reliably contains 2.7mg (THC)/2.5mg (CBD). Dosage will be titrated up to a maximum dose of 4 sprays per day (10.8mg THC/10mg CBD). This will be administered over the maximum duration of 4 weeks

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal spray
Routes of administration	Oromucosal use

Dosage and administration details:

Sativex placebo will be administered using the same device (oromucosal spray), and contain ethanol, propylene glycol (50:50), with peppermint oil (.05%) flavourings and colourings. The Placebo will follow the same dosing schedule as the experimental (Sativex) arm and will be administered over the maximum duration of 4 weeks.

Number of subjects in period 1	Sativex	Placebo
Started	15	14
Completed	15	14

Period 2	
Period 2 title	Overall Trial (Both Arms combined)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Arm title	Overall Trial (Both Arms Combined)
Arm description: -	
Arm type	Both arms
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Overall Trial (Both Arms Combined)
Started	29
Completed	29

Baseline characteristics

Reporting groups	
Reporting group title	Sativex
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Sativex	Placebo	Total
Number of subjects	15	14	29
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	83.0	81.0	
inter-quartile range (Q1-Q3)	77 to 86	75.0 to 87.0	-
Gender categorical Units: Subjects			
Female	9	5	14
Male	6	9	15

End points

End points reporting groups

Reporting group title	Sativex
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Overall Trial (Both Arms Combined)
Reporting group description: -	

Primary: Follow-up rate

End point title	Follow-up rate[1]
End point description:	
End point type	Primary
End point timeframe:	
Week 4 and Week 8	

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: Please see uploaded report

End point values	Overall Trial (Both Arms Combined)			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: 29				
Week 4	29			
Week 8	29			

Statistical analyses

No statistical analyses for this end point

Primary: CMAI completion rate

End point title	CMAI completion rate[2]
End point description:	
End point type	Primary
End point timeframe:	
Week 4 to Week 8	

Notes:

[2] - 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: Please see uploaded report

End point values	Overall Trial (Both Arms Combined)			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: 29				
Week 4	29			
Week 8	28			

Statistical analyses

No statistical analyses for this end point

Primary: Participant Adherence

End point title	Participant Adherence[3]

End point description:

End point type	Primary

End point timeframe:

Weeks 1 – 4

Notes:

[3] - 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: Please see uploaded report

End point values	Overall Trial (Both Arms Combined)			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: 29	29			

Statistical analyses

No statistical analyses for this end point

Primary: Randomisation rate

End point title	Randomisation rate[4]

End point description:

End point type	Primary

End point timeframe:

Screening period

Notes:

[4] - 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: Please see uploaded report

End point values	Overall Trial (Both Arms Combined)			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: 29	29			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 to Week 8	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	Sativex
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Sativex	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)	1 / 14 (7.14%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Sativex	Placebo	
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 15 (26.67%)	2 / 14 (14.29%)	
Eye disorders Eye disorders subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 14 (7.14%) 1	
Hepatobiliary disorders Hepatobiliary disorders subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	1 / 14 (7.14%) 1	
Respiratory, thoracic and mediastinal disorders Respiratory disorders subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	
Skin and subcutaneous tissue disorders Skin/tissues disorders subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 14 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 April 2021	Protocol V4.0, 07-Apr-21
11 May 2022	Protocol Version 5.0: - Upper age limit increased to 95yrs - Change in blood screening conditions

Notes:

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/40479610