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Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register: Last refreshed on: Main ID:		JPRN 2 April 2019 JPRN-JMA-IIA00303								
Date of registration:		18/07/2017								
Prospective Registration: Primary sponsor: Public title: Scientific title: Date of first enrolment: Target sample size:		No Hirohisa Ono Dementia treatment with combination of hydrogen gas and reduced dose lithium. A combined treatment for Alzheimer's dementia with hydrogen gas inhalation and reduced dose lithium. A randomized controlled clinical study. 18/02/2017 50								
Recruitment status:		Recruiting								
URL: Study type:		https://dbcentre3.jmacct.med.or.jp/jmactr/App/JMACTRE02_04/JMACTRE02_04.aspx?kbn=3&seqno=7011 INTERVENTIONAL								
Study design:		Randomized allocation. Type of control:ACTIVE or STANDARD TREATMENT. Randomized: YES. Randomization unit:INDIVIDUAL. Blinding: SINGLE BLIND. Method of allocation concealment: OTHER. Purpose:SAFETY,EFFICACY.								
Phase:		NOT APPLICABLE								
Countries of recruitment										
Japan										
Contacts Name:	Hirohisa Ono		Name:	Hirohisa Ono						
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Affiliation: Nishijima Hospita		al de la constante de la const	Affiliation:	Nishijima Hospital						

Key inclusion & exclusion criteria

Inclusion criteria: Alzheimer's dementia patient with confirmed worsening of clinical symptoms, MMSE score and ADAS score. Exclusion criteria: Dementia patient affected by other type of dementia rather than Alzheimer type, severe functional abnormality in the kidney, liver, pancreas and uncontrolled diabetes, lipidemia and hypertension.

Age minimum: >=45 YEARS Age maximum: <=95 YEARS Gender: BOTH

Health Condition(s) or Problem(s) studied

Alzheimer's dementia

Intervention(s)

Intervention type:DRUG. Intervention1:H2 gas inhalation, Dose form:INHALANT, Route of administration:ORAL, intended dose regimen:3%H2 for 1hr BID by natural breathing. 200mg Li tablet BID. Control intervention1:control group, Dose form:TABLET, Route of administration:ORAL, Intended dose regimen: donepezil 5mg BID

Primary Outcome(s)

Neurological improvement and improvements in MRI indices. Timepoint:6 months after initiation of the study..

Secondary Outcome(s)

Secondary ID(s) Nill Known

Source(s) of Monetary Support

Self-funding

Secondary Sponsor(s)

Yoji Nishijima Ethics review

Status:

Approval date: Contact:

Results

Results available: Date Posted: Date Completed: URL:

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