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:	JPRN
Last refreshed on:	2 April 2019
Main ID:	JPRN-JMA-IIA00303
Date of registration:	18/07/2017
Prospective Registration:	No
Primary sponsor:	Hirohisa Ono
Public title:	Dementia treatment with combination of hydrogen gas and reduced dose lithium.
Scientific title:	A combined treatment for Alzheimer's dementia with hydrogen gas inhalation and reduced dose lithium. A randomized controlled clinical study.
Date of first enrolment:	18/02/2017
Target sample size:	50
Recruitment status:	Recruiting
URL:	https://dbcentre3.jmacct.med.or.jp/jmactr/App/JMACTRE02_04/JMACTRE02_04.aspx?kbn=3&seqno=7011
Study type:	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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Telephone:	+81-55-922-8235	**Telephone:**	+81-55-922-8235
Email:		**Email:**	hirohisa.ono@live.jp
Affiliation:	Nishijima Hospital	**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
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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:	