SAM study: An epigenetic therapy for depression after childhood trauma

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21753

Source
Nationaal Trial Register

Brief title
SAM study

Health condition

bipolar disorder; depression; DNA methylation; childhood trauma; SAMe; S-adenosyl-L-methionine; epigenetic

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
Source(s) of monetary or material Support: ZonMw, Hersenstichting

Intervention

Outcome measures

Primary outcome

50 percent reduction of 50% or more of the Hamilton Depression Rating Scale

Secondary outcome

MADRS, genome-wide DNA methylation and KITLG methylation, Altered stress resilience

Study description

Background summary

A clinical trial on effects of SAMe on depression and DNA methylation in bipolar disorder patients with a history of childhood trauma. In the Netherlands.

Study objective

We hypothesize that the epigenetic changes that are related to childhood trauma provide a treatment target for succesful treatment with SAMe of persistent depression in bipolar disorder

Study design

T0 before intervention, T1 immediately after invention, and 6 months monthly follow-up.

Intervention

S-adenosyl-L-methionine 12 weeks, oral, 1200 mg daily, versus placebo

Contacts

Public
Geertje De Lange
Utrecht
The Netherlands
+31 88 755 0695
Scientific
Geertje De Lange
Utrecht
The Netherlands
+31 88 755 0695

Eligibility criteria

Inclusion criteria

1. Diagnosis of bipolar disorder as defined by DSM-IV-R as determined by the SCID.

2. Age 18 -65 years.

3. Stable medication use (in the last 6 months).

4. Current depressive episode as defined by a HAM-D score of at least 16.

5. High levels of childhood trauma measured by the CTQ (Bernstein et al., 2003).

6. Suitable for EMDR treatment.

7. Capable of providing written informed consent.

Exclusion criteria

1. Psychiatric admission in the past six months

2. Compulsory admission or treatment under Dutch law (BOPZ)

3. Major somatic disorder interfering with treatment or diagnosis

4. Pregnancy or breastfeeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6147
NTR-old	NTR6302
Other	ABR : 62020

Study results