Triple chronotherapy (combined total sleep deprivation, sleep phase advance and bright light therapy) to reduce acute depressive and suicidal symptoms: a randomized controlled clinical trial

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Study Ongoing

Administrative details

EU PAS number

EUPAS30637

Study ID

50737

DARWIN EU® study

No

Study countries

☐ Italy

Study status

Ongoing

Research institutions and networks

Institutions

ASST Santi Paolo e Carlo

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Institution

Contact details

Study institution contact

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Primary lead investigator

Armando D'Agostino

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/07/2018

Actual: 20/07/2018

Study start date
Planned: 03/12/2018

Actual: 03/12/2018

Data analysis start date
Planned: 01/04/2021

Date of interim report, if expected
Planned: 30/06/2021

Date of final study report
Planned: 01/06/2023

Sources of funding

- Other

More details on funding

unfunded study

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To assess the efficacy of a Triple Chronotherapy add-on intervention in patients hospitalized for a Depressive Episode. Triple Chronotherapy includes Sleep Deprivation (SD) - Sleep Phase Advance (SPA) and Bright Light Therapy (BLT).

Study drug and medical condition

Medical condition to be studied

Depression suicidal

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

75

Study design details

Outcomes

50% change from baseline associated with Triple Chronotherapy add-onintervention in the Hamilton Depression Rating Scale (HAMD-17) score, 50% score reduction of HAMD-17, reduction of suicidality at the Nurses' Global Assessment of Suicide Risk (NGASR) and Columbia Suicide Severity Rating Scale (C-SSRS), improved sleep quality assessed by the Pittsburgh Sleep Quality Index (PSQI), Length of Stay (LoS)

Data analysis plan

Continuous variables will be described as means and standard deviation after Kolmogorov-Smirnov normality check. Non-normal variables will be described as medians and quartiles. Multiple imputation will be employed for missing data.Multivariate models will be used for between-groups comparisons. Binary logistic regression will be used with a dichotomous score based on the primary outcome to discern responders from non-responders. Goodness-of-fit and effect size will be evaluated and confidence intervals set at 95%

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No