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

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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:

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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