Lithium and Standard Therapy in Resistant Depression (LAST)

This study is currently recruiting participants.

Verified by Universita di Verona, June 2009
First Received: June 24, 2009 No Changes Posted

Sponsored by:	**Universita di Verona**
Information provided by:	Universita di Verona
ClinicalTrials.gov Identifier:	NCT00927550

Purpose

The principal clinical question is whether **lithium** is effective in reducing the risk of suicidal behaviour in subjects with treatment-resistant depression and suicide risk. Additionally aims of the study are: (a) to assess whether **lithium** is effective in improving depressive symptomatology in subjects with treatment-resistant depression and suicide risk; (b) to assess the tolerability profile of **lithium**.

Condition	Intervention	Phase
Depression	Drug: **lithium** Drug: usual care	Phase IV

Study Type: Interventional

Study Design: Treatment, Randomized, Open Label, Active Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Randomized Evaluation of the Effectiveness of **Lithium** in Subjects With Treatment-Resistant Depression and Suicide Risk. An Independent,

Pragmatic, Multicentre, Parallel-Group, Superiority Trial.

Resource links provided by NLM:

MedlinePlus related topics: Depression Suicide

Drug Information available for: Lithium carbonate Lithium citrate

U.S. FDA Resources

Further study details as provided by Universita di Verona:

Primary Outcome Measures:

- Suicide completion and acts of deliberate self harm (DSH) will constitute the composite primary outcome. [Time Frame: one year] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- All-cause mortality. Suicide mortality. Deliberate self-harm or attempted suicide. Change in severity of depressive symptoms from baseline. Adverse reactions during the study. [Time Frame: one year] [Designated as safety issue: Yes]

Estimated Enrollment:	230
Study Start Date:	June 2009
Estimated Study Completion Date:	December 2012
Estimated Primary Completion Date:	December 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
lithium plus usual care: Experimental	Drug: **lithium**
usual care without lithium therapy: Active Comparator	Drug: usual care

▶ Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Diagnosis of major depression (clinical diagnosis, guided by DSM-IV criteria).
- History of attempted suicide or deliberate self-harm in the previous 12 months.
- Inadequate response to at least two antidepressants given sequentially at an adequate dose for an adequate time for the current depressive episode.
- Uncertainty about which treatment arm would be best for participant.
- Age 18 or above.
- Agreement between investigator and patient to enter the study.

Exclusion Criteria:

- In addition to major depression, a primary diagnosis of any concurrent Axis I disorder (according to DSM-IV criteria) will constitute an exclusion criterion; by contrast, any concurrent Axis II disorder (according to DSM-IV criteria) will not constitute an exclusion criterion.
- Previous exposure to lithium was associated with lack of efficacy or unwanted adverse reactions.
- Clinical conditions contraindicate the experimental treatment arm (for example thyroid or kidney disease or abnormalities).
- Pregnant/lactating women.
- Women of childbearing potential not practicing a reliable method of contraception.

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00927550

Contacts

Contact: corrado barbui, MD	+39 04581 26418	mailto:corrado.barbui%40univr.it?subject=NCT00927550, LAST_RD_FARM77Z3BL-5.1_132009, Lithium and Standard Therapy in Resistant Depression

Locations

Italy

University of Verona — **Recruiting**
verona, Italy, 37134

Contact: Corrado Barbui, MD
mailto:corrado.barbui%40univr.it?subject=NCT00927550, LAST_RD_FARM77Z3BL-5.1_132009, Lithium and Standard Therapy in Resistant Depression
Principal Investigator: Andrea Cipriani, MD
Principal Investigator: Corrado Barbui, MD
Principal Investigator: Michela Nosè, MD
Principal Investigator: Marianna Purgato, Psychologist
Principal Investigator: Francesca Girlanda, Psychologist
Principal Investigator: Eleonora Esposito, MD

Sponsors and Collaborators

Universita di Verona

Investigators

Study Chair: Michele Tansella, MD, Professor of psychiatry University of Verona

▶ More Information

No publications provided

Responsible Party:	University of Verona (Corrado Barbui MD)
Study ID Numbers:	LAST_RD_FARM77Z3BL-5.1_132009
Study First Received:	June 24, 2009
Last Updated:	June 24, 2009
ClinicalTrials.gov Identifier:	NCT00927550 History of Changes
Health Authority:	Italy: Agenzia Italiana del Farmaco

Keywords provided by Universita di Verona:

resistant depression
lithium
RCT
lithium therapy
standard therapy
resistant depression

Study placed in the following topic categories:

Depression
Tranquilizing Agents
Psychotropic Drugs
Suicide
Lithium Carbonate
Central Nervous System Depressants
Depressive Disorder
Antipsychotic Agents
Antimanic Agents
Behavioral Symptoms
Mental Disorders
Mood Disorders
Antidepressive Agents
Lithium

Additional relevant MeSH terms:

Lithium
Lithium Carbonate
Depression
Tranquilizing Agents
Molecular Mechanisms of Pharmacological Action
Physiological Effects of Drugs
Psychotropic Drugs
Depressive Disorder
Antipsychotic Agents
Pharmacologic Actions
Behavioral Symptoms
Mental Disorders
Therapeutic Uses
Mood Disorders
Central Nervous System Agents

Central Nervous System Depressants
Enzyme Inhibitors
Antimanic Agents

Antidepressive Agents

ClinicalTrials.gov processed this record on July 02, 2009

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