Optimization of Treatment and Management of Schizophrenia in Europe

What is the OPTMISE trial?

The optimise trial is a large European study, that aims to find the best way to treat people with psychosis, using many options that are available and study new medication. Fourteen countries, all headed by an expert in the field of schizophrenia research, are involved. A total of 350 patients with a first psychosis can participate in the study. The study is financially supported by the European Union.

What is psychosis?

Someone may have psychotic symptoms if he or she has very strong convictions that are not shared by other people, or if a person sees, feels or hears things that other people cannot perceive. The most common type of psychosis is schizophrenia, which is a brain disease that involves a disturbance in thoughts, perceptions and cognition. Some people only experience one psychotic episode from which they recover well. For others, schizophrenia is a long-term illness for which medication and psychosocial interventions can help to control the symptoms and help patients to get on with their lives.

What happens during the study?

The optimal way to use the existing antipsychotic medications will be investigated, and in some countries a new potential medicine is studied. Many medicines are available, and different people respond differently to these medicines. Part of the patients will recover from the first medication they are prescribed, but some patients don't and they may need to switch to other medication. In this study we investigate if amisulpride would be a good choice as first treatment. 350 patients will use this medicine for 4 weeks. In a previous study, amisulpride was found to be effective against psychosis and induce only few side effects. If patients do not recover sufficiently, we then study whether it is better to switch to another medication (olanzapine) or to use amisulpride for 6 more weeks. Patients who have not recovered on amisulpride are assigned by chance to either amisulpride or olanzapine and use this medication for 6 weeks. Some patients may also not recover after 10 weeks of treatment with either amisulpride for 10 weeks, or amisulpride followed by olanzapine. These patients may need to switch to a stronger medicine, clozapine. This medicine will be used for 12 weeks. This way we aim to offer the best possible treatment using the antipsychotic drugs that are already available. During this study, information from molecules in the blood is used to predict which patients will respond well to which medication. Some patients will also be asked to make one or more brain scans. Information from that MRI scan is also used to predict treatment response.

When a patient responds well to the medication, he or she can participate in a second 12-week part of the study. During this part, it is investigated whether certain

psychosocial interventions, such as web-based text messages and family information may help the patient to remain healthy after the first psychosis. These interventions are aimed at increasing medication adherence. Only 50% of the patients will receive the intervention, which is assigned by chance. After this 12-week part of the study, patients are asked to come back a few times during the next 40 weeks, to check how he or she is doing.

Another 150 patients can participate in a separate trial, which will investigate the antipsychotic properties of cannabidiol, a derivate of the cannabis plant. This separate trial will be conducted in Germany, and possibly in Denmark and Romania.

Is participation voluntary?

Participation in this study is entirely voluntary. Patients are free to decide whether or not to participate. This decision will not affect the clinical care that patients receive in any way. If one decides to participate, one is free to withdraw from the study at any time and for whatever reason. There is no payment involved for patients who decide to participate.

Who can participate?

There are some criteria that participants need to meet before they may participate. Some of these criteria are listed below. If a patient is interested, all criteria need to be discussed with the treating physician.

A patient needs to:

- be between 18 and 40 years of age
- have a diagnosis of schizophrenia, schizophreniform disorder or schizoaffective disorder

A patient cannot participate if he/she:

- has experienced psychotic symptoms for longer than 2 years
- has used antipsychotic medication for longer than 6 weeks during your life, or longer than 2 weeks in the past year
- she is pregnant of breastfeeding

Are there benefits for participants?

There are no direct benefits for participating patients. However, the following factors may be helpful in receiving optimal care for a first psychotic episode:

- regular contact with the treatment team; weekly for the largest part of the study
- close monitoring of treatment and recovery
- when participants do not recover sufficiently within a set timeframe, other treatment options are implemented swiftly, while in daily practice it usually takes longer before other options are explored
- when participants do recover within a set timeframe, they may have the opportunity (50% chance) to try a new psychosocial intervention that may increase medication adherence
- participants help in developing optimal treatment guidelines for all patients experiencing psychotic symptoms

Can I get additional information?

If you are interested in (participating in) this study (and you are currently treated in one of the centres listed below), please contact the study personnel and feel free to ask all the questions you may have (for specific contact information, please refer to www.optimisetrial.eu, section 'The Group') .

Austria
Medical University Innsbruck

Belgium
Universitair Centrum St.-Jozef

Czech Republic:
- Psychiatrická klinika LF UK
- Psychiatrické centrum Praha

Denmark:
- Psychiatric University Centre Glostrup
- Psychiatric Center Copenhagen

France:
Institut National de la Santé et de la Reserche Médicale (INSERM)

Germany:
- Central Institute of Mental Health
- Technische Universität München
- Ludwig-Maximilians University Munich

Israel:
Sheba Medical Centre

Italy:
University of Naples SUN

Netherlands:
University Medical Center Utrecht

Poland:
University of Medical Sciences

Romania:
Tangent Data (tel: 021 3233224)

Spain:
- Hospital General Universitario Gregório Marañon
- Hospital Clínico San Carlos
- Instituto de Investigación Hospital 12 de Octubre
- Universidad de Oviedo
- Hospital Clinic i Provincial

Switzerland:
Privatklinik für Psychiatrie und Psychotherapie Oetwil am See/Zürich

UK:
- King's College London
- University of Manchester