BETTER-B

German Version

The BETTER-B Main Trial: An International, Multicentre, Randomised Controlled Pragmatic Phase III Trial of Mirtazapine to alleviate Breathlessness in Palliative and End of Life Care

Project leader: Priv.-Doz. Dr. Steffen Simon
Contact person: Dr. Anne Pralong
Duration: 02/2019 – 01/2023
Funding institution: Horizon 2020/Societal challenges (EU project)
Contact: anne.pralong@uk-koeln.de

Project description

The BETTER-B consortium tests whether mirtazapine, currently used as an antidepressant, is an effective treatment to reduce chronic or refractory breathlessness (CB) in patients with advanced chronic obstructive pulmonary or interstitial lung disease (COPD or ILD) needing palliative care or at the end of life. Our focus is on breathlessness that persists despite optimal treatment of the underlying condition. This widespread and frightening symptom has a major detrimental impact on patients’ quality of life and distresses their family, friends and carers. It is associated with physical and psychosocial morbidity and results in high use of health care services, including emergency care.

A feasibility trial in 60 patients, reviews and case studies have already been completed, that suggest mirtazapine is a promising treatment.

To assess if mirtazapine is effective, we conduct a randomised double blind clinical trial of mirtazapine versus placebo in patients with CB and COPD or ILD. The trial recruits 324 patients over 18 months across respiratory, palliative care and community services in Poland, Ireland, Italy, Germany and the UK. At the University Hospital of Cologne (including Bethanien Hospital in Solingen) as one of the two recruitment centres in Germany (in cooperation with LMU in Munich), we plan to recruit 30 patients. We study the effects of treatment over time on patients, their family or caregivers and care costs. We survey clinicians and produce accessible European guidance on treating CB.

The consortium unites a unique multi-disciplinary and international group of clinician scientists from respiratory, palliative, geriatric and rehabilitation fields, alongside statisticians, trialists, health economists, health care researchers, patient and consumer groups. This ensures the
optimal design and operation of the trial and the widest impact from its results. Using an existing medicine for a different purpose offers a highly cost-effective approach for treatment that can be implemented and sustained internationally.

Further Information