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## Introduction

A proinflammatory state in a subgroup of depressed patients has been reported repeatedly (e.g. increased interleukin-6 and tumour necrosis factor- $\alpha$ ). COX-2 inhibitors down-regulate increased inflammatory markers and are therefore investigated as an add-on therapy in depression. Proinflammatory cytokines and/or kynurenine metabolites may predict the outcome of treatment with COX-2 inhibitors.

## Objectives

To prove or disprove the hypothesis of a better therapy response in the group of add-on celecoxib to sertraline, particularly in patients with a more pronounced proinflammatory state at baseline. The aim is to find a biological predictor (cytokines and/or kynurenine metabolites) for treatment outcome.

## Design

This is a dual-center, randomized, double-blind, placebo-controlled, parallel group phase IIa study. It investigates the mean change in clinical outcome and in serum cytokine and kynurenine levels from baseline to endpoint (week 6) in patients with major depression (HAMD-17  $\geq$  22) treated with sertraline plus celecoxib versus sertraline plus placebo for six weeks. 51 depressed patients of both gender, aged between 18 and 60 years without any recent inflammatory disease were enrolled. The study comprises six study visits (6x ratings, 3x blood collections) during six weeks of treatment and a follow-up visit 10 weeks after baseline. Cytokines were measured by Enzyme-linked Immunosorbent Assay (ELISA), kynurenine and its metabolites by High Performance Liquid Chromatography (HPLC).

## Results and Conclusion

The study was completed quite recently and the results are in progress.