

1.0 Abstract

Title

Study P12-705

Reveal the Level of Anxiety in Patients with Crohn's Disease receiving Adalimumab (RELAX)

Keywords

Monoclonal, anxiety, antibodies, Adalimumab, severe Crohn's disease, Quality of Life, biological products

Rationale and Background

Several studies have already proven to ameliorate the emotional/psychological status of patients such as Quality of Life and depression using TNF- α antibodies. Our current study aims were to primarily show eventual positive effect on the anxiety level of patients as a result of being in therapy with Adalimumab for severe active Crohn's Disease (CD).

Research Question and Objectives

Primary Objective was to describe and evaluate the change of the level of anxiety assessed by the State Trait Anxiety Index (STAI) and Hospital Anxiety and Depression Scale (HADS) from baseline to after 6 months of treatment with Adalimumab in patients with severe CD.

Further objectives of this study were to describe the effect of Adalimumab on the correlation between anxiety and health related quality of life and clinical status, respectively. Therefore the short Inflammatory Bowel Disease Questionnaire (sIBDQ) and the Harvey-Bradshaw Index (HBI) were applied.

Study Design

This is a non-interventional, observational study conducted in a prospective, single-country, multicenter format.

Setting

Eight centers with a high level of experience in the treatment of Crohn's disease patients and the conduct of non-interventional studies.

Subjects and Study Size, Including Dropouts

Eighty-three patients with active severe Crohn's disease which required immunosuppressive treatment were recruited.

Visit 2 (Week 12 visit) was performed for 54 (65%) patients and Visit 3 (Week 24 visit) was performed for 73 (88%) patients.

Variables and Data Sources

For assessment of the present level of disease activity and quantification of symptoms of patients with Crohn's disease the HBI was applied.

For assessments of anxiety and depression the STAI and the HADS were applied. Health related Quality of Life was assessed by the sIBDQ.

All patient data entered by the investigational sites in the patient's electronic case report form was forwarded for evaluation to Data Management.

Results

Primary Objectives

State-Trait Anxiety Inventory (STAI)

Comparing State (S) scores between visits over all patients revealed a statistically significant reduction from Visit 1 to Visit 2 and no statistically significant changes from Visit 1 to Visit 3 and from Visit 2 to Visit 3 respectively.

Comparing Trait scores between visits over all patients revealed no statistically significant change between any two visits.

Hospital Anxiety and Depression Scale (HADS)

For the HADS Anxiety score, no statistically significant changes overall were observed between any two visits.

For the HADS Depression score, no significant changes overall were observed between any two visits.

Secondary Objectives

Short Inflammatory Bowel Disease Questionnaire (sIBDQ)

Comparing sIBDQ scores between visits for all patients revealed statistically significant increases from Visit 1 to Visit 2 and from Visit 1 to Visit 3.

Harvey-Bradshaw Index (HBI)

For all patients significant increases of remission from Visit 1 to Visit 2 and from Visit 1 to Visit 3 could be observed. Safety

Ten Serious Adverse Events were reported for 9 (10,8%) patients. Safety findings were in line with the expected safety profile of Adalimumab and the underlying Crohn's disease treated.

Discussion

Patients improved according to STAI (S), sIBDQ and HBI. Female patients improved significantly better than male patients in STAI (S) score and sIBDQ.

Marketing Authorisation Holder(s)

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