CASE STUDY
Inflammatory Bowel Disease

Study description
Multicentre open label study, phase II, Simon's optimal two- stage design to preliminary evaluate efficacy and tolerability of the association of x + x in the tenesmus treatment in patients suffering from distal ulcer colitis.

Study objective
The primary aim was to assess clinical efficacy of X+ X solution in patients suffering from distal ulcer colitis presenting tenesmus.

Patient population
26 patients

Treatment period
7 (14) days of open-label treatment: evaluation of the primary endpoints on day 5° and follow-up up to day 15° from the beginning of the treatment.

Primary Efficacy parameter
Total regression of the tenesmus symptoms.
Secondary: to evaluate the effect of the therapy on the quality of life of patients and its tolerability.

Study details
Total number of patients: 26
Recruitment period: 1 months
First patient in: June 11 2007
Last patient out: July 12 2007

Sintesi Research Services
Project management, regulatory, site coordination, investigators and CRA meetings, data management, QA QC, medical final report.

Key challenges
- The Sponsor gave Sintesi one month to include 20 patients.
- The customer required a very fast recruitment.
- The customer wanted to close the database as soon as possible and wanted to include 26 patients to reach the target. Since recruitment rate performed was very scarce, the customer asked Sintesi Research to enquiry about the possibility to open two highly potential sites abroad.
- The fast recruitment has also required a very performing data management system enabling the customer to have in a very short time clean data.
- The study also required the completion of diaries to assess the quality of life and the performance of a pharmacy-economics analyses.

Keys of project success

During the start up phase in selecting countries we have considered the existence of completive trails.

To optimize recruitment a detailed pre-assessment of the patients clinical records (considering above all concomitant therapies).

Sintesi Research has performed a strict and precise monitoring activities to control regularity of activities.

To maximize and accelerate patients recruitment Sintesi Research performed a very exact country and sites evaluation and selected highly experienced and motivated investigators.

Sintesi Research staff has closely worked with the sites keeping regular contacts also by performing weekly teleconferences for a quick update on the study.

To discover Sintesi Research services contact us.

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