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The ADEOS trial End of Study Report
RR08/8685
EudraCT Number: 2008-004877-17

A prospective, single-centre, double-blind, randomised, placebo-controlled trial evaluating efficacy of Adalimumab + Methotrexate versus Placebo + Methotrexate in Patients with Early Oligoarthritis ADEOS: ADalimumab in persistent Early Oligoarthrits Study

The research team at the University of Leeds conducted and carried out the ADEOS study as per protocol in line with what was agreed in terms of protocol adherence, trial design, study objectives and study hypothesis. The aim of the ADEOS trial was to compare combination therapy with adalimumab and methotrexate to methotrexate monotherapy in the management of early, persistent oligoarthritis.

The ADEOS trial commenced on 8th December 2011, and the last patient last visit occurred on 16th January 2017. Due to slower recruitment as a result of lack of eligible patients, a substantial amendment to the protocol was approved on 2nd July 2013 to reduce the total number of patients from 30 to 24, and the recruitment period and end of trial date extended. In all, of the 24 patients that were finally proposed within the application, 39 patients were screened; 17 patients failed screening, with 22 patients who were eventually recruited during this time period.

Following the close-out visit for ADEOS, a preliminary source data verification (SDV) was conducted of all trial data for 15/22 randomised patients and 3/17 screen failures. For each study visit, issues relating to any of the data points collected on the source paper worksheet, the eCRF, study procedures, adverse events and medications have been fully documented. These full reports have been inspected by our internal monitor who raised some queries on the preliminary SDV; these have been addressed for 2/15 randomised patients.

A meeting between the statistician, research nurse, monitor and trial coordinator, during which all of the SDV findings available were reviewed, highlighted some issues with eligibility assessment, study visit scheduling, outcome completion and documentation of medication.

Across all of the 15 patients reviewed, each one of these issues (some of which had already been discussed in isolation) was not particularly severe, but when considered in combination, it was felt that the overall data integrity of the trial was not sufficient to justify the resources required to continue the SDV process. Therefore it was decided that the study will not proceed towards publication of data.

Yours sincerely

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