

Ciclosporin in the management of ENL reactions

Data Creators

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Data Description

Data produced as part of a clinical trial to compare the efficacy and safety of Ciclosporin and Prednisolone in the Treatment of Erythema Nodosum Leprosum (ENL). The trial was conducted with two randomised, double blind, controlled groups in Ethiopia. The first group had acute first time occurrence of ENL and the second group had recurrent ENL. Both groups were randomized to one of two study arms: the ciclosporin treatment arm or the prednisolone treatment arm. Patients were followed over a 32 week period, where they were assessed for changes in clinical signs and adverse events.

Data Collection Methods

Data from each assessment was recorded on standardised Patient Record Forms (PRF) and kept in a set of case notes separate from other hospital record. Data was verified and entered into Case Record Forms (CRF) by the study physicians. Double data entry into a Microsoft Access 2007 database was performed by Saba Lambera and a data manager at ALERT/AHRI.

Data Analysis and Preparation

The double entry was then verified using Epi-Info 3.5.4. The initial rate of errors detected by double entry was just under 10%. Errors in the data were verified and corrected in Ethiopia. Errors were traced back to the CRFs and correct. Epi-info was re-run and procedures repeated until two identical and correct databases were obtained.

The following MS Access data tables were subsequently transferred to SPSS v20 for analysis:

1. Registration
2. FU general
3. FU skin
4. FU nerve
5. FU monofilament
6. FU VMT
7. FU SF36
8. FU Investigations
9. FU Histology
10. FU Adverse
11. FU termination

Geographic regions

Addis Ababa, Ethiopia, Africa

Key dates

Data capture began on August 12 2011 and ended May 10th 2012. Data entry and analysis was performed following this activity.

Quality Controls

Quality controls on the data and project in its entirety were implemented by the appointed Data Safety and Monitoring Board and the study trial monitor.

Species:

Human population

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Privacy:

All patients were only identifiable by a unique study number. The study forms were kept in a set of case notes separate from other hospital record. All study records were kept in a locked area accessed only by two nominated study staff.

Ethics

Ethical approvals obtained are listed below:

1. London School of Hygiene and Tropical Medicine Ethics Committee, approval numbers: 5376, 5377 and 5378
2. AHRI/ALERT Ethical Review Committee, project number: P005/08
3. National Science and Technology Ethics Review Committee of Ethiopia approval number: RDHE/34-90/2009
4. Drug Administration and Control Authority of Ethiopia. Clinical trial authorization number: 02/12/79/926.

Keywords

Leprosy, leprosy reaction, Erythema Nodosum Leprosum, adverse events, ciclosporin, prednisolone

Language of written material

English

Project Information

Project

Ciclosporin in the management of acute and chronic ENL

Assessing Ciclosporin in the Treatment of Leprosy Reactions: Evidence from a Randomized Controlled Trial and Other Studies (PhD)

Funder/Sponsor

Hospital and Homes of St Giles

Grant Number

ITCRBY24

Associated Roles

Role	Forename	Surname	Faculty / Dept	Institution
Data Creator, data collector and Project leader	Saba	Lambert	Faculty of Infectious and Tropical Diseases / Dept of Clinical Research	London School of Hygiene & Tropical Medicine
Data base creator	Peter	Nicholls		University of Southampton
Data Management	Laurence	Yamuah	Data management	Armauer Hansen Research Institute in Ethiopia
Project Leader	Diana	Lockwood	Faculty of Infectious and Tropical Diseases / Dept of Clinical Research	London School of Hygiene & Tropical Medicine
Data Collector	Digafe	Tsegaye	Dermatology Dept	ALERT hospital
Data Collector	Shimelis	Nigusse	Dermatology Dept	ALERT Hospital

File Description

Title	Filename	File type	Description
CnT1R and CnENL Protocol & Standard Operating Procedures	CiclosporinReactionStudy-SOP	Adobe PDF/A	Protocol and SOP of study
Erythema Nodosum Leprosum (ENL) Database	ENL DATABASE 6.02.14 final.mdb	Microsoft Access	Anonymised dataset of analysis performed in the treatment of Erythema Nodosum Leprosum (ENL)