AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

PRODUCT: AZD8593
ACTIVE INGREDIENT: None (this is a MeMo study)

Study No: D0960M00006
A Feasibility Study to Collect Data in Patients with Haemophilia - A multi centre study with no treatment, designed to gain information about the haemophilia patient population

Developmental Phase: MeMo
Study Completion Date: 2009-06-26
Date of Report: 2010-02-15

OBJECTIVES:

The objectives of the study were:

- To gain information about disease-specific clinical characteristics for future reference.
- To collect and store blood samples for potential future exploratory research in haemophilia

METHODS:

Laboratory variables related to coagulation and Serious Adverse Events in connection to blood sampling procedures were collected. Non-serious Adverse Events were not recorded.

Indicators of concentration:

Coagulation Factor

Prothrombinase

Indicators of activity:

Thrombin generation, Calibrated Automatic Thrombogram (CAT)

Clot method with deficient plasma

Analysis of antibody to coagulation factors.

RESULTS:

The study gave valuable information regarding the epidemiology, disease-specific clinical characteristics and the present status of medication as well as presence and history of inhibitors against coagulation factors, in 50 patients with haemophilia in Sweden.

The patients received relatively intense medical treatment, and the number of bleeds were low. Only a few patients had received transfusion of erythrocytes during the 5 year period preceding the study. More than half of the patients received tranexamic acid.

Hepatitis C was very common (32 patients) and HIV was also relatively common (5 patients).

The mean ETP level was approximately 70% of what was seen in a normal control population.