AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Zoladex 3,6 mg
ACTIVE INGREDIENT: goserelinum

Study No: NIS-ORO-ZOL-2008/1
ESIS Study Non-Interventional Study to evaluate **E**ffect of Zoladex In Endometrio**SIS**

Developmental phase: Post-marketing - Non-interventional study

Study Completion Date: not-completed/ stopped on September 2009

Date of Report: No report; due to low recruitment rate the study was stopped and no data analysis have been made.

OBJECTIVES:

- ***Primary objective:***

The primary objective of the study is to observe the effect of goserelin 3,6mg sc depot injection by assessment of the mean percent reduction scores for symptoms: dysmenorrhoea, dyspareunia and pelvic pain at 4, 8, 12,16 and 20 weeks compared with scores recorded in visit 1(week 0).

- ***Secondary objective***:

The secondary objective of the study is to observe the effect of goserelin 3,6mg sc depot injection by assessment of the mean percent reduction scores for pelvic tenderness and indurations at 20 weeks, compared with scores recorded in visit 1(week 0).

- ***Tertiary objective***:

The tertiary objective of the study is to observe the reduction in the proportion of patients requiring analgesics for the relief of pelvic pain at 4, 8,12,16 and 20 weeks, compared with scores recorded in visit 1(week 0).

METHODS:

The programme will include the patients diagnosed with endometriosis that the doctors have already decided to treat with Zoladex within the last month, before inclusion in this program. The patients will be treated and will follow current routine medical practice (physical examination, previous and concomitant medication), adverse events during all 6 visits specified in the protocol.

The treatment will consist in administration of goserelin 3,6mg sc depot injection at 28 days for 20 weeks.

RESULTS:

Due to low recruitment rate (21 patients included out of 105) no data analysis was performed.