Synopsis of study report: 151/97
Location in Module 5:

Study Code:
BY217/FK1 002

Report Date:
28-Jan-1998

Title of the study:

Acute bronchospasmolytic effect of 0.5 and 1 mg B9302-107 po in subjects with bronchial asthma.

Study center(s):

Innovex GmbH, Obere Hardtstr. 8-16, D-79114 Freiburg

Publication (reference):

Not available

Studied period (years):

04 November 1996 – 19 March 1997

Clinical phase:

II

Objectives:

- To study the extent, onset and duration of bronchodilation after oral intake of 0.5 and 1 mg roflumilast in comparison with placebo in volunteers with mild to moderate asthma.
- To study the safety and tolerance of roflumilast.

Methodology:

The study followed a double-blind, randomized three-period change-over design. Single doses of placebo as well as 0.5 mg and 1 mg roflumilast were administered, separated by washout intervals of 1 to 2 weeks. FEV_1 was recorded before as well as 15, 30, 45, 60, 90, 120, 180,

240, 300 and 360 min after intake of the trial medication. By then 0.2 mg of a short-acting bronchodilator was inhaled and a final FEV_1 value was recorded.

No. of subjects (total and for each treatment):

Intention-to-treat: n = 15
Per-protocol: n = 12

Diagnosis and criteria for inclusion:

Subjects with mild to moderate bronchial asthma (FEV_1 = 50-90% predicted), age 18-45 years, caucasians, non-smokers.

Duration of treatment:

Single dose

Test product:

Roflumilast

Dose:

0.5 mg roflumilast
1 mg roflumilast

Mode of administration:

p.o.

Batch No.:

0.5 mg: 101396/1
1 mg: 102396/1

Reference product:

Placebo

Dose:

Not applicable

Mode of administration:

po

Batch No.:

103396/1

Criteria for evaluation:

Primary parameter: FEV_1 time average 0-1 h and 0-6 h po.

Secondary parameters: Safety (laboratory work-up, adverse events, physical examination, ECG, BP, HR).

Statistical methods:

Page-test, one-sided.

SUMMARY – CONCLUSIONS

The present study suggests that single doses of 0.5 and 1 mg roflumilast do not improve FEV_1 up to 6 hours after drug intake.

A single dose of 1 mg roflumilast was associated with adverse events such as headache, dizziness and nausea, whereas 0.5 mg was well tolerated.