COMPARATIVE STUDY

FUCIDIN® FILM-COATED TABLETS VERSUS PYOSTACINE®
IN THE TREATMENT OF SKIN INFECTIONS.

SUMMARY

In a multicentre, comparative, randomised, open study, the clinical and bacteriological effectiveness and clinical safety of oral fusidic acid (FA) (film-coated tablets) were compared to pristinamycin (P) to treat skin infections suitable for oral treatment.

Two daily doses of FA at a usual dosage of 1 g (group II) and a reduced dosage of 500 mg (group I) were compared to the usual dosage of 2 g of P (group III).

This study, reserved for patients of at least 12 years of age, did not include ulcer infections, surgical wounds, pilonidal cysts, erysipelas and infections where no bacteriological sampling was possible; patients with a known intolerance to FA or P, who were pregnant or breast-feeding, with known hepatic failure, who received antibiotic therapy in the 5 previous days of non-established inefficacy, requiring a combined antibiotic therapy, or for whom adherence to the protocol might be questionable.

273 patients were thus recruited. 90 in groups I and II, 93 in group III.

The population in the three groups, two-thirds of whom were male, with an average age of 36 and weighing 66 kg, proved to be homogeneous apart from four parameters (statistically significant difference), two of which had no clear effect on the safety or efficacy: less complex condition combined with the infection in group III; more frequent pain in group II. On the other hand, the higher proportion of infections involving a gram-negative bacteria in group I and the bacteria’s long in vitro FA sensitivity in the groups treated with this antibiotic compared to P in its treatment arm, was also taken into account in the assessment of efficacy.

The infection being treated was primary in two thirds of the cases (boils, impetigo, abscesses, etc.), while it was a superinfection (of eczema, a wound or other) in one third of cases.

The bacteria was isolated in nearly 90% of the cases, Staphylococcus aureus (SA) in nearly two thirds, Coagulase Negative Staphylococci (CNS) 12 to 20% depending on the group, Streptococci a little more than 10%, gram-negative bacteria 14.6% in group I and 5% in the two other groups. There was no significant difference in the bacteria’s sensitivity to FA and P between the three groups (resistance to FA of the order of 9% and 6% for P).

The average nine-day antibiotic therapy was, in approximately 20% of cases, combined with a surgical procedure at inclusion, in 15% of cases with a general treatment (analgesics, anti-inflammatories, etc.) and in 80% of cases with a local antiseptic with the following results:

As regards efficacy, with an assessable group of 85, 84 and 84 patients (groups I, II and III respectively), this revealed, without a statistically significant difference between the groups: 69.4, 73.8 and 70.2% healed, 22.4, 25.0 and 26.2% improved and 8.2, 1.2 and 3.6% failed.

The difference however became significant in terms of success or failure if one excluded 2 cases (groups II and III) that had an unfavourable result after incorrect treatment (half dose). Group I had...
significantly more failures than the other two groups (p = 0.0496). There did not appear to be any difference in efficacy between the two groups, with the exception of impetigo, which healed significantly better in group II (100%) (p < 0.02) than in the other two groups: 43.8% (I) and 50.0% (III); nor was there any difference according to the initial bacteria in question. However, there is still a doubt about the streptococci isolated 4 times (2 before, 2 after) in the group I failures.

From a bacteriological point of view, after treatment (an examination carried out in 50% of cases with the isolation of the bacteria in half of these cases), significantly more CNS were noted after FA (theoretically non pathogens): 53.8, 37.5 and 14.3% respectively for Groups I, II and III, and more SA after P: 30.8, 20.8 and 76.2% respectively, with sensitivity to pristinamycin retained. However, there is still the question of recurrences for this antibiotic and bacteria.

A treatment in addition to the antibiotic therapy was administered in approximately 405 of cases in each group, without a difference in the types of treatment administered.

With 9.1% of cases reporting an unwanted side effect (USE) in group I, 12.6% in group II and 28.6% in group III, the clinical safety was significantly higher in the groups treated with FA (p < 10^-2). The percentage of treatments discontinued: 2.3, 4.6 and 9.9%, was not, statistically speaking, significantly different (p = 0.08).

All in all, with clinical safety very significantly higher to that of pristinamycin, fusidic acid, administered at the normal dosage of 4 daily tablets demonstrates a clinical and bacteriological efficacy that is at least the same, despite the reservation regarding in vitro sensitivity of the bacteria to FA being lower than that of P. This justifies the usual reservation towards skin smears, rarely conducted in practice.

The lowest dose, administered to group I, while demonstrating very good safety, had a failure rate that was very slightly higher (but of only borderline statistical significance) to that of the two other groups. The presence of streptococci in 4 of the 7 failures in this group could suggest insufficient tissue concentrations at the dose used for a bacteria less sensitive than staphylococcus, thus favouring a daily dose of 4 tablets in group II for infections likely to be caused by this bacteria.