SYNOPSIS

TABLE OF CONTENT

2.1 PROTOCOL SUMMARY

2.2 RESULTS

2.2.1 Study population

2.2.2 Efficacy results

2.2.3 Compliance with study medication - Other treatments

2.2.4 Safety evaluation

2.2.5 Treatment cost

2.3 DISCUSSION

2.4 CONCLUSIONS
2 SYNOPSIS

2.1 PROTOCOL SUMMARY

Study code: FUT 9501 FR

Title: Efficacy of a 7.5 days course of oral Fusidic acid in the treatment of skin infections.

A comparison of sodium fusidate (Fucidin® tablets 250 mg) 500 mg twice daily for 7.5 days and Pristinamycin (Pyostacine 500® tablets 500 mg) 1 g twice daily for 10 days.

Primary study objective
To study the overall clinical effect of a 7.5 days course of oral Fusidic acid in the treatment of bacterial skin infections.

Secondary study objectives
1) Bacteriological effect, 4) Global patient impression,
2) Symptomatic response, 5) Cost effectiveness.
3) Safety,

Study design and treatments
French, multicentre, prospective, randomised, parallel-group, double blind study.

Patients were randomly assigned to receive either:
- a 7 and a half days course of Fucidin®, 2 tablets twice daily (1 g/d) (total 30 tablets) or,
- a 10 days course of Pyostacine 500®, 2 tablets twice daily (2 g/d) (total 40 tablets).

The Fucidin® course was completed by placebo until 10 days. Placebo tablets of Pyostacine 500® in the Fucidin® group (Gp) and vice versa allowed the respect of the double blind.

Patients were reviewed on days 11 and 25 (visits (V) 2 and 3 respectively) (or form returned by the patient in case he/she can not come at this visit).
2.2 PROTOCOL SUMMARY (CONTINUED)

Sample size: a minimum of 320 analysable patients were required to detect a minimal difference of 10% in response rate between the two treatments.

Eligibility criteria:

Inclusion criteria: out-patients from dermatology practice (hospital or private), of either sex (contraception for women of child bearing potential), aged 18 years or more, with skin infection for which oral antibacterial therapy is indicated, e.g., carbuncle, acute folliculitis, abscess, paronychia, impetigo, traumatic wound infection....) and having given signed informed consent.

Exclusion criteria: erysipelas, cellulitis, chronic/recurrent furonculosis, post-operative wound infections, cutaneous ulcers, pilonidal cyst; pre-existing dermatosis; no possible bacteriological sampling; known intolerance to one of the used treatments; history of liver disease; non equilibrated diabetes; immunodepression; possibly unable to comply with the protocol: alcoholic, drug abuser or psychotic subject; systemic or topical antibiotic in the previous week; concurrent systemic corticotherapy; treatment not yet approved for clinical use within 3 months prior to visit 1; pregnant or wishing to become or breast feeding women; people deprived of their freedom by judicial or administrative decision; major under supervision; patient staying in a social or sanitary establishment or in emergency condition; previous randomisation in this trial; concurrent participation in any other clinical study.

Primary Criterion of response
The investigator's overall clinical response 'cured' after the course of treatment.

Assessments: see table next page.

Adverse events: reported by patients or observed by the Investigator.
STUDY DIAGRAM AND PROCEDURES

Fusidic acid group

V1 Randomisation
10 days treatment

Pristinamycin group

V2 15 days follow-up
V3

active Fusidic acid (FA)  Fusidic acid placebo
active Pristinamycin (P)  Pristinamycin placebo

<table>
<thead>
<tr>
<th></th>
<th>Visit 1 (Day 1)</th>
<th>Visit 2 (Day 11 ± 1)</th>
<th>Post-treatment follow-up (Day 25 ± 2)</th>
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<td>Clinical assessment of lesions</td>
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<td>Overall clinical response</td>
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<td>Assessment of relapse</td>
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<td>-</td>
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<td>Recording of adverse events</td>
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<tr>
<td>Collection of used/unused trial medication</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td></td>
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</tr>
</tbody>
</table>

1 only required for those patients who have pathological material present

2 Visit 3 was only required for those patients who do not need a complementary antibiotherapy at visit 2; it was before in case of relapse. In case of absence of the patient at this visit, a mail was sent by the Investigator to the patient in order to get a post-treatment efficacy and safety evaluation and global patient's impression.
2.2 RESULTS

2.2.1 Study population.

2.2.1.1 Recruitment and Randomisation (See Figures 1 and 2).

Figure 1: Number of patients attending each visit

![Diagram of patient visits and data collection](attachment:Figure1.png)

(1) Visit 3 could be an attended visit or a postal response.

(2) Two patients had no primary efficacy data.

(3) In a case, no visit 2, information by phone; failure because of premature withdrawal due to side effect.

Figure 2: Schematic presentation of the patient populations

![Diagram of patient populations](attachment:Figure2.png)

(1) In a case, no visit 2, information by phone; failure because of premature withdrawal due to side effect.
2.2.1 Study population. (continued)

2.2.1.2 Demographic and other baseline characteristics (all randomised patients).

2.2.1.2.1 Demographics.

The mean age of patients in the FA Gp (40.1 years) was slightly higher than in the P Gp (36.2 years). The two Gps were well balanced at baseline in terms of sex (61.3% males for FA, 62.0% for P), mean weight (68.7 kg for FA, 71.2 kg for P), mean height (170.3 cm for FA, 171.5 cm for P) and other diseases (49.4% and 41.6% respectively).

2.2.1.2.2 Disease Characteristics.

The treatment Gps were generally well balanced for these characteristics. (See table).

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>All randomised patients</th>
<th>FA (n=168)</th>
<th>P (n=166)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N*</td>
<td>%</td>
<td>N*</td>
</tr>
<tr>
<td>Furuncle</td>
<td>60</td>
<td>18.0</td>
<td>32</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>69</td>
<td>20.7</td>
<td>34</td>
</tr>
<tr>
<td>Abscess</td>
<td>88</td>
<td>26.3</td>
<td>42</td>
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<tr>
<td>Whitlow</td>
<td>9</td>
<td>2.7</td>
<td>7</td>
</tr>
<tr>
<td>Impetigo</td>
<td>56</td>
<td>16.8</td>
<td>28</td>
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<tr>
<td>Wound</td>
<td>17</td>
<td>5.1</td>
<td>7</td>
</tr>
<tr>
<td>Other</td>
<td>38</td>
<td>11.4</td>
<td>20</td>
</tr>
<tr>
<td>One diagnosis</td>
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<td>99.1</td>
<td>166</td>
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<tr>
<td>More than one diagnosis</td>
<td>3</td>
<td>0.9</td>
<td>2</td>
</tr>
</tbody>
</table>

* N: number of patients

Previously used antibiotics for the infection: 5 patients (3.0%) in the FA Gp compared to 11 (6.6%) in the P Gp. The median number of days between last administration of antibiotic to visit 1 was about 3 weeks in both groups.
2.2.1 Study population. (continued)

2.2.1.2 Demographic and other baseline characteristics. (continued)

2.2.1.2.2 Disease Characteristics. (continued)

Most of the clinical signs and symptoms at baseline did not differ markedly between the two treatment Gps.

- **Severity of the infection:** most lesions were of moderate severity: 66.7% of the FA Gp, 68.1% of the P Gp (severe: 12.5% and 14.5% respectively).
- **Median duration of the lesion:** 7 days in both treatment Gps.
- **Fever** (temperature ≥ 38°C): for only a few patients 3.0% (FA) and 4.8% (P).
- **Redness:** 97.0% (FA) and 95.2% (P).
- **Oedema:** 63.7% (FA) and 69.3% (P).
- **Spontaneous discharge:** 42.9% (FA) and 44.8% (P).
- **Purulent discharge:** 57.5% (FA) and 57.3% (P).
- **Pain:** the most common assessment was moderate, 36.9% (FA), 34.3% (P).
- **Heat feeling from the lesion:** 56.0% (FA) and 51.8% (P).
- **Proportion of patients requiring surgery:** 25.0% (FA) and 24.7% (P).

More patients in the FA Gp had loco-regional extension (26.2%) compared to the P Gp (18.1%).
2.2.1 Study population. (continued)

2.2.1.2 Demographic and other baseline characteristics. (continued)

2.2.1.2.3 Bacteriology at baseline

<table>
<thead>
<tr>
<th>Pathogen isolated</th>
<th>All randomised patients (n=334)</th>
<th>FA (n=168)</th>
<th>P (n=166)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
</tr>
<tr>
<td>No pathogen</td>
<td>44 13.3</td>
<td>18 10.8</td>
<td>26 15.7</td>
</tr>
<tr>
<td>Pathogen isolated</td>
<td>288 86.7</td>
<td>148 89.2</td>
<td>140 84.3</td>
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<tr>
<td>Total</td>
<td>332 100.0</td>
<td>166 100.0</td>
<td>166 100.0</td>
</tr>
</tbody>
</table>

1) Patients can have more than one pathogen isolated

Susceptibility of *Staphylococcus aureus*:

- FA: 93.8% (93.7% in the FA Gp and 93.9% in the P Gp).
- P: 96.3% (97.5% and 95.2% respectively).

Resistance of *Staphylococcus aureus*:

- FA: 1.9% (intermediate sensitivity 4.3%) and P: 3.1%.
- Penicillin: 70.4% (74.7% and 66.3% respectively).
- Oxacillin: 13% (11.4% and 14.5% respectively).
- Erythromycin: 32.7% (39.2%, 26.5% respectively).

Susceptibility of the *Streptococcus* isolates:

- FA: 31.3% (4 in the FA Gp and 6 in the P Gp).
- P: 75.0% (70.6% and 80.0% respectively).
- Penicillin: 75.0% (76.5% and 73.3% respectively).
- Erythromycin: 71.9% (70.6% and 73.3% respectively).
2.2.2 Efficacy results.

Investigators' assessment of overall clinical treatment response of visit 2. The difference between the two treatment Gps was not statistically significant.

<table>
<thead>
<tr>
<th>Global response to treatment</th>
<th>FA</th>
<th></th>
<th>P</th>
<th></th>
<th>Difference between treatment Gps</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>Difference (95% C.I.) P-value</td>
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<tr>
<td>Cured</td>
<td>128</td>
<td>79.7</td>
<td>118</td>
<td>76.1</td>
<td>3.6 (-5.6 to 12.8) P=0.44</td>
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<tr>
<td>Failed</td>
<td>32</td>
<td>20.3</td>
<td>37</td>
<td>23.9</td>
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<td></td>
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<tr>
<td>Total</td>
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<tr>
<td>Cured</td>
<td>123</td>
<td>80.4</td>
<td>116</td>
<td>76.3</td>
<td>4.1 (-5.2 to 13.3) P=0.39</td>
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<tr>
<td>Failed</td>
<td>30</td>
<td>19.6</td>
<td>36</td>
<td>23.7</td>
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<tr>
<td>Total</td>
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<tr>
<td>Cured</td>
<td>66</td>
<td>79.5</td>
<td>67</td>
<td>78.8</td>
<td>0.7 (-11.6 to 13.0) P=0.91</td>
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<tr>
<td>Failed</td>
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<td>18</td>
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<td>100.0</td>
<td>85</td>
<td>100.0</td>
<td></td>
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</tr>
</tbody>
</table>

1) Chi-squared test

2.2.2.1 Changes in the clinical parameters (ITT population).

The distribution of changes was similar in the two treatment Gps for all the studied items. For the patients with the sign or symptom present at baseline, the difference in the percentage of cured/improved patients was the following:

- **Investigators' assessment of overall severity:** 0.8% (89.8 % FA - 89.0 % P); 95% C.I. -6.0 to 7.6 (P=0.82).
- **Redness:** 3.5% (64.5% FA - 61.0% P); 95% C.I. -7.5 to 14.5 (P=0.53).
- **Oedema:** 3.8% (81.2% FA - 77.4% P); 95% C.I. -7.2 to 14.9 (P=0.50).
- **Discharge:** 1.4% (81.7% FA - 80.4% P); 95% C.I. -9.2 to 11.9 (P=0.80).
- **Pain:** -4.3% (90.8% FA - 95.1% P); 95% C.I. -10.5 to 2.0 (P=0.18).
- **Feeling of heat:** -7.5% (86.7% FA - 92.4% P); 95% C.I. -14.9 to 3.4 (P=0.23).

The need for surgical intervention was similar in both treatment Gps (P=0.96).
2.2.2 Efficacy results. (continued)

2.2.2.2 Patients' overall satisfaction (ITT population).
The distribution of patients' overall satisfaction with treatment was statistically,
significantly different between the two treatment Gps (P = 0.04): 47.1% of
patients very satisfied in the FA Gp and 31.8% in the P Gp.

2.2.2.3 Bacteriological response (Bacteriologically evaluable population).
('Success': eradication or presumptive eradication or a different pathogen).
Bacteriological success rate: 85.2% in the FA Gp and 82.7% in the P Gp (p = 0.67).

2.2.2.4 Follow-up results (patients 'cured' at V2).

2.2.2.4.1 Global response.

ITT: 'Cure' maintained: 92.6% in FA Gp and 90.4% in P Gp (see table).

<table>
<thead>
<tr>
<th>Global response to treatment</th>
<th>FA</th>
<th>P</th>
<th>Difference between treatment groups</th>
<th>N</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>(95% C.I.)</th>
<th>P-value</th>
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<tr>
<td>INTENTION TO TREAT</td>
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<td>Cured</td>
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</tbody>
</table>
2.2.2.4 Follow-up results (patients 'cured' at V 2). (continued)

2.2.2.4.2 Bacteriological response at V3 (Bacteriologically evaluable population with a 'success' at V2). ('Relapse': presence of S. aureus or streptococcus at V3)

No relapse: 50 (96.2%) in the FA Gp and 40 (88.9%) in the P Gp.
Difference in the percentage of patients with no relapse (FA - P): 7.3%; 95% C.I. - 3.3% to 17.8 (P=0.24)

2.2.2.4.3 Patients' satisfaction with treatment at V3.
Percentage of patients very satisfied: FA Gp, 52.9%; P Gp, 45.1% (P=0.68).

2.2.3 Compliance with study medication - Other treatments.
- Compliance was higher in the FA Gp (71.4%) than in the P Gp (62.7%).
  Mean number of taken doses: 14.4 ± 1.8 (FA) and 18.5 ± 3.7 (P), i.e. 7.2 ± 0.9 days of treatment in the FA Gp and 9.2 ± 1.9 days in the P Gp.
- Concurrent medication for other diseases at baseline: 31.5% patients in the FA Gp and 23.5% patients in the P Gp.

2.2.4 Safety evaluation (Safety population; FA: 162 patients; P: 156; see 2.2.1.1).

Adverse events unlikely to be related to study treatment: 19 patients (11.7%) in the FA Gp experienced 23 adverse events versus 18 (11.5%) in the P Gp who experienced 22 adverse events.

Adverse events possibly or probably related to study treatment: 20 patients (12.3%) in the FA Gp experienced 35 adverse events versus 48 (30.8%) in the P Gp who experienced 67 adverse events.

The difference in the proportion of patients was statistically significant (P<0.001). The largest difference between the treatment Gps was in the 'diarrhoea, flaccid stools' category in which 3 (1.9%) patients in the FA Gp had events compared to 21 (13.5%) in the P Gp.
2.2.4 Safety evaluation (continued).

Adverse events possibly or probably related to study treatment: among 35 events in the FA Gp, 13 were 'severe', 10 were 'moderate' and 12 were 'mild'; among 67 events in the P Gp, 16 were 'severe', 21 were 'moderate' and 30 were 'mild'.

Premature withdrawals due to adverse events: 6 patients (3.6%) in the FA Gp prematurely withdrawn the study (relation to the treatment possible (1) or probable (5)) versus 14 (8.4%) in the P Gp (relation to the treatment possible (2) or probable (12)).

One serious adverse event was reported in one patient of the FA group.

2.2.5 Treatment cost.

The difference in the cost between the two treatments was calculated for the patients with available data after visit 1 i.e. for the safety population.

This cost took into account the actual cost of the antibiotic treatment, FA or P, the cost of complementary medication due to the infection after visit 1, the cost of surgery after the third day of treatment due to the infection and the cost of the complementary medication and hospitalisation due to adverse events (prices according to the French drugs dictionary (1999) and to the official norms in 1999 for surgery and hospitalisation).

Treatment cost per patient: 443 FF (FA) (293 FF if the hospitalisation is excluded) and 545 FF (P). The P treatment was 23% more expensive than the FA treatment for the studied parameters as a whole (about 80% more without the hospitalisation cost).
2.3 Discussion.

The first study objective was to study the overall clinical efficacy of a 7.5 days course of oral FA in treatment of community acquired bacterial skin infections. It was secondly to assess the bacteriological efficacy, the symptomatic response, the safety, the patient's satisfaction and the cost effectiveness.

Baseline characteristics of the patients showed that the population recruited in this study was similar to the one recruited in other studies with the same indications (3-4, 13).

A S. aureus was isolated in 48.8% of the patients, and a streptococcus in 10% of the patients, in accordance with other studies. Resistance rate to FA was 1.9%, lower than in the previous study versus P (2) and 4.3% of the strains were of intermediate susceptibility. The resistance rate to P was 3.1% in accordance with the one registered in other studies (2, 4).

At baseline, the two treatment groups were well balanced regarding most of the characteristics, including the bacteriological data.

There was no statistically significant difference between the two treatment groups for the high response rate to treatment: in the ITT population, at the end of the treatment, 79.7% of the patients were "cured" in the FA group and 76.1% in the P group and respectively 92.6% and 90.4% of the patients cured had no relapse after 3 weeks follow up. The clinical success rates were similar for the PP population, for the staphylococcal and streptococcal infections, and also for the bacteriological success rate: respectively 85.2% and 82.7% (end of treatment) and 96.2 and 88.9% (3 weeks).

These results were obtained with a better patients' overall satisfaction with the treatment in the FA group, 47.1% (FA) and 31.8% (P).
2.3 Discussion. (continued)

In accordance with other studies (2,4), the tolerance was statistically better for FA, with 12.3% of patients with adverse events possibly or probably related to treatment versus 30.8% for P. The largest difference between the treatment groups was in the 'low digestive disorders' category in which 2.5% of the patients in the FA group had adverse events compared to 16.7% in the P group.

The effects of FA or P, efficacy or safety, observed in the present study were comparable with the ones reported in other studies (4, 13).

The global cost of the treatment was favourable to FA, the P treatment being 23% more expensive than the FA treatment.

2.4 Conclusions.

It is concluded that there was no clinically or statistically significant difference between the efficacy of a Fusidic acid 7.5 days treatment (1 g a day) and of a Pristinamycin 10 days treatment (2 g a day) in the treatment of acute superficial skin infection. However, in the Fusidic acid group, patients' overall immediate satisfaction was better and the treatment cost was lower. Moreover, Pristinamycin treatment was associated with significantly more reports of adverse events.

A Fusidic acid 7.5 days treatment is therefore a good and safe alternative to a Pristinamycin 10 days treatment in the treatment of in community acquired acute skin infection of known or suspected bacterial origin.