

# Evaluation of the efficacy and safety of the fixed drugs combination in tuberculosis

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## Background

- The use of the fixed drugs combination (FDC) has been recommended for the first time in 1994 by the World Health Organization in the treatment of tuberculosis.
- The aim of our study was to compare the efficacy and safety of FDC to the dissociated form for the treatment of extra-pulmonary tuberculosis (EPT).

## Materials/Methods

- Retrospective study: n= 341 cases
- Department: Infectious Diseases
- Period: between 1995 and 2013
- The cases were divided into 2 groups:  
G1: treated by the FDC (G1 =60; 17.6%)  
G2: treated by the dissociated form (G2 = 281; 82.4%).

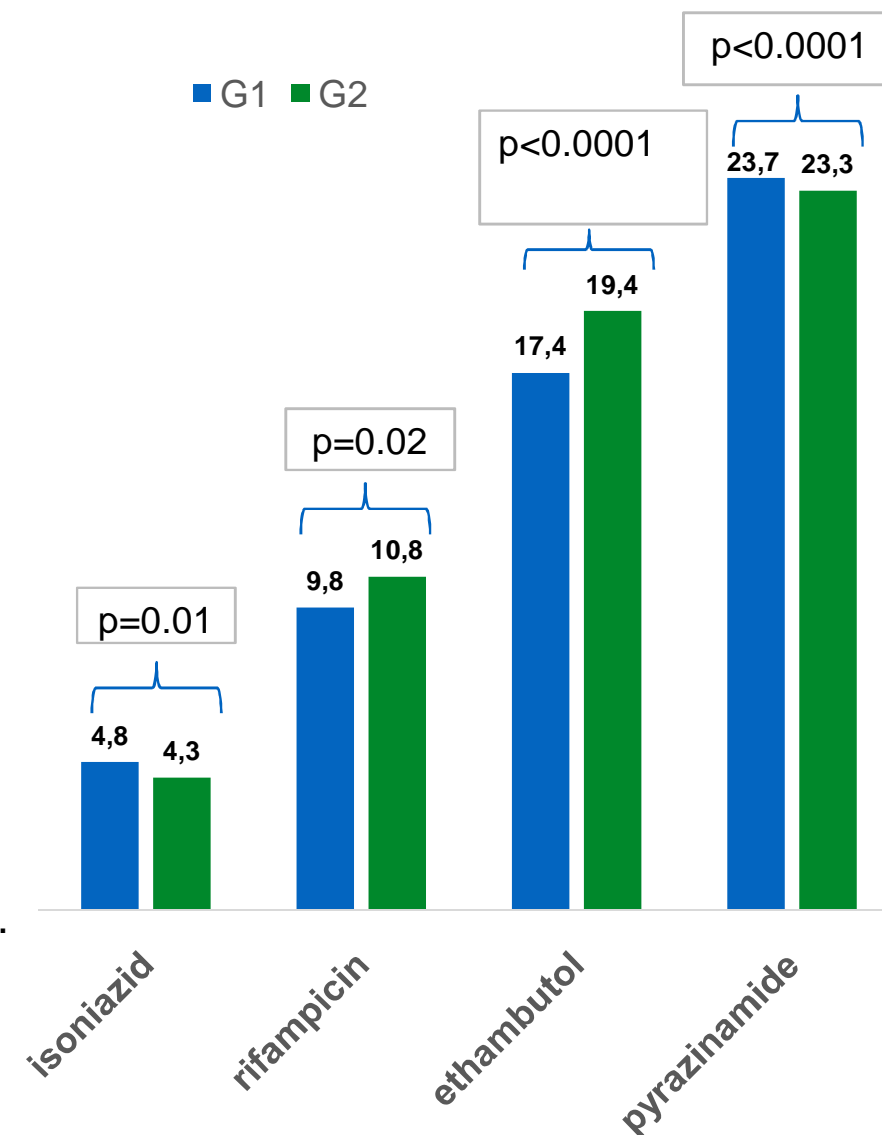
## Results

- Mean age: G1: 38.6 ± 20.2 years  
G2: 42.5 ± 19.1 years
- Females: G1: 34 cases (56.7%), G2: 166 cases (59%); (p = 0.7)
- Lymph node: the most frequent localization (G1 = 51.7%, G2 = 31.3%; p = 0.03) (Table1)

**Table1:** the main localizations of EPT in the 2 groups

| Localization    | Groups |        | P           |
|-----------------|--------|--------|-------------|
|                 | G1 (%) | G2 (%) |             |
| Lymph node      | 51.7   | 31.3   | <b>0.03</b> |
| Bone            | 6.7    | 18.9   | <b>0.02</b> |
| Neuro meningeal | 6.7    | 22.8   | <b>0.05</b> |
| Uro-genital     | 5      | 16.7   | <b>0.02</b> |

- The average dose in mg/kg: significantly different between G1 and G2 (figure1)



**Figure1:** comparison of TB treatment doses in G1 and G2

- TB Treatment duration significantly higher in G2 (p<0.0001)  
G1: 11.2 ± 4 months  
G2: 13.6 ± 6.3 months
- Hospital stay: significantly lower in G1: (p<0.0001)  
G1: 6.8 ± 8.3 days  
G2: 19.4 ± 16.8 days

- Good tolerance of treatment: 75% for G1 and 61.5% for G2 (p = 0.048)
- Treatment side effects: More frequent in G2 (table2)

**Table2:** Different TB treatment side effects in G1 and G2

| Side effect            | Groups |        | P     |
|------------------------|--------|--------|-------|
|                        | G1 (%) | G2 (%) |       |
| Neurological disorder  | 5      | 16.9   | 0.018 |
| Hematological disorder | 0      | 2.5    | 0.2   |
| Anaphylactic reaction  | 1.7    | 1.8    | 0.9   |
| Liver cytolysis        | 10     | 14.7   | 0.3   |

- The most implicated drug in the occurrence of side effects: isoniazid in 74 cases (21.7%), pyrazinamide in 54 cases (12.8%), rifampicin in 39 cases (11.4%) and ethambutol in 16 cases (4.7%).

- Healing: 88.9% with no statistical difference between the 2 groups (G1 = 87.7%, G2 = 92.2%; p = 0.2). (Table3)

**Table3:** Disease evolution in the 2 groups

| Evolution         | Groups |        | P    |
|-------------------|--------|--------|------|
|                   | G1 (%) | G2 (%) |      |
| Cure              | 87.7   | 92.2   | 0.2  |
| Complicated forms | 16.4   | 29     | 0.05 |
| Sequelae          | 16.7   | 18.7   | 0.7  |
| Relapse           | 5      | 6.5    | 1    |

## Conclusion

- The FDC treatment was as well tolerated as dissociated form.
- In addition it allows to simplify and avoid errors in prescribing, to increase treatment compliance and subsequently to prevent the emergence of drug resistance.