Importance of residual Investigational Medicinal Product count

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BACKGROUNG

Good clinical Practice in clinical trials specify the role of the pharmacist. For each nominative dispensation, the pharmacist is responsible to the education of the patient on the treatment, residual Investigational Medicinal Product (IMP) count, and thus the evaluation of the compliance

PURPOSE

The objective of this study is to assess the importance of pharmaceutical vigilance about IMPs

MATERIALS AND METHODS

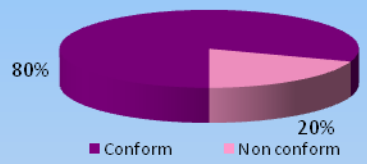
This prospective study has been realized during three months.

For each nominative dispensation, a count of returned treatment (RT) by the patient from the previously dispensation was performed to assess compliance.

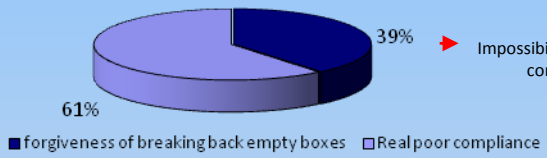
RESULTS

117 returned treatment analyzed

Proportion of non conformity of Investigational Medicinal Product's returns



Reasons of non conformity of Investigational Medicinal Product's returns



1 clinical trial not included = 43 RT

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23 RT non conform = 48.9%

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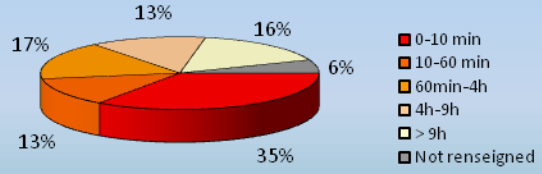
Impossibility to evaluate compliance:
- posology changes not notified to the pharmacy
- unsuitable secondary packaging

Time management of returned treatment (n=117)



Average counting time = 12 minutes (5-30 min)

A returned IMP exact count was operated during the dispensation for 34% of RT

In all cases, a global analysis of RT was performed before the dispensation

CONCLUSIONS

This study points out the major role of the pharmacist in the education of the patient enrolled in clinical trials, about the return of all experimental medication and therapeutic schedule. It appeared very important to evaluate compliance during the act of dispensation, independently of the time consumed (12 min) in order to correct on time, possible errors of medication intake

Keys words: Good clinical Practice, clinical trials, compliance

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