Telaprevir in patients with genotype 3 HCV
Eudract 2013-003729-27

Summary

Objective

The primary objective was to determine whether patients with genotype 3 HCV and cirrhosis who have relapsed following therapy with PegIFN and riba will achieve a sustained virological response if treated with telaprevir, pegylated interferon and ribavirin

The secondary objective was to determine whether pre-treatment viral phenotyping predicts the response to therapy with telaprevir in patients with G3 HCV and cirrhosis

Design

Open label multi-centre study aiming to enrol 30 patients

Results

The trial was discontinued early as new treatment regimens for patients with genotype 3 hepatitis C were released rendering this approach obsolete. A total of 14 patients were enrolled of whom 4 (29%) achieved a sustained response. In the 10 patients who could be phenotyped the response was 66% (2 of 3) in patients predicted to respond and 14% in patients predicted not to respond. This did not reach a level of statistical significance. The treatment was associated with a large number of non-serious side effects.

Conclusion

Telaprevir may be clinically effective in patients with genotype 3 HCV and cirrhosis who have failed to respond to pegylated interferon and ribavirin and viral phenotyping may play a role. However larger studies will be required to confirm this observation and the availability of alternative, more effective treatments renders this approach non-viable.

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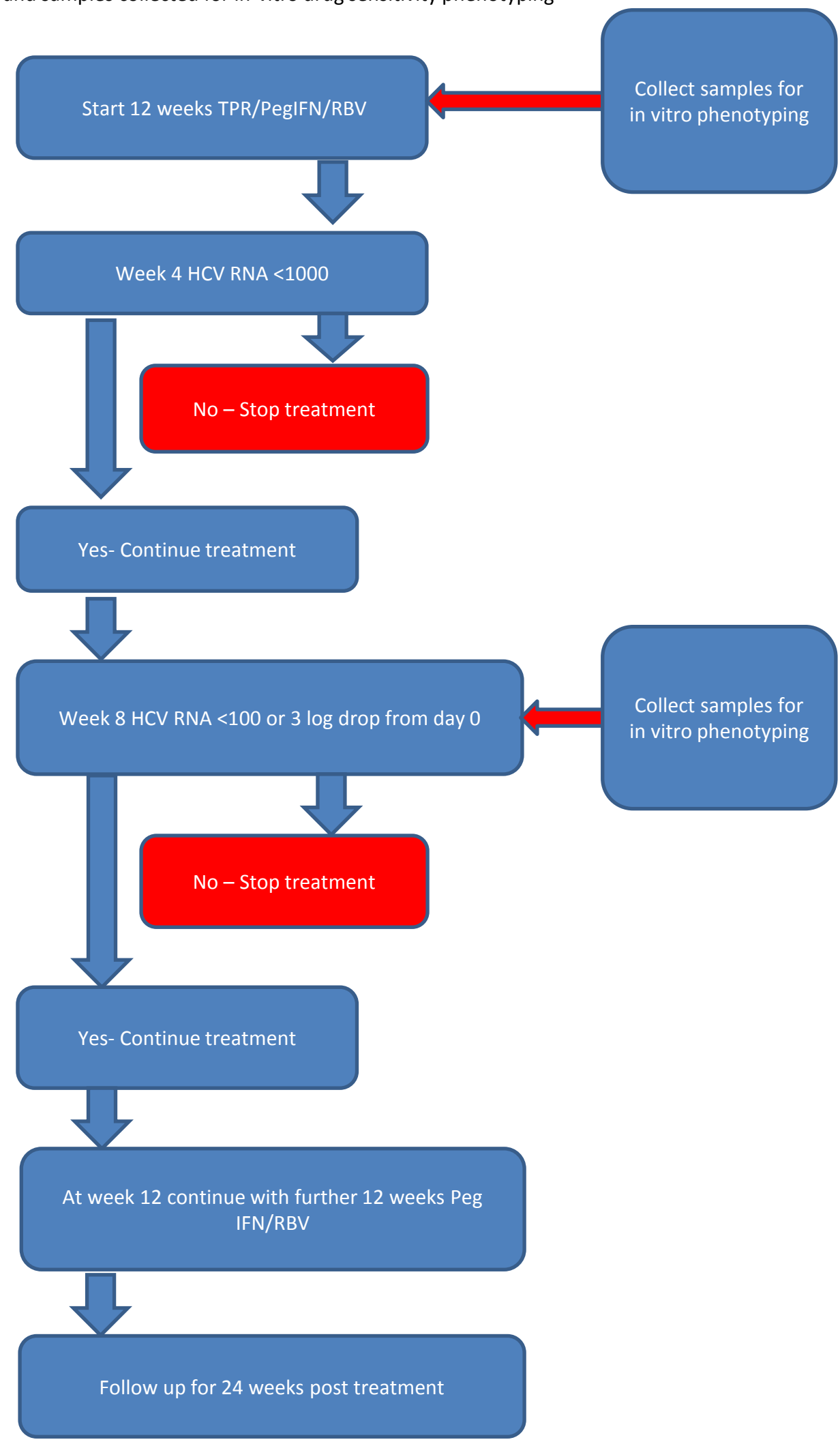
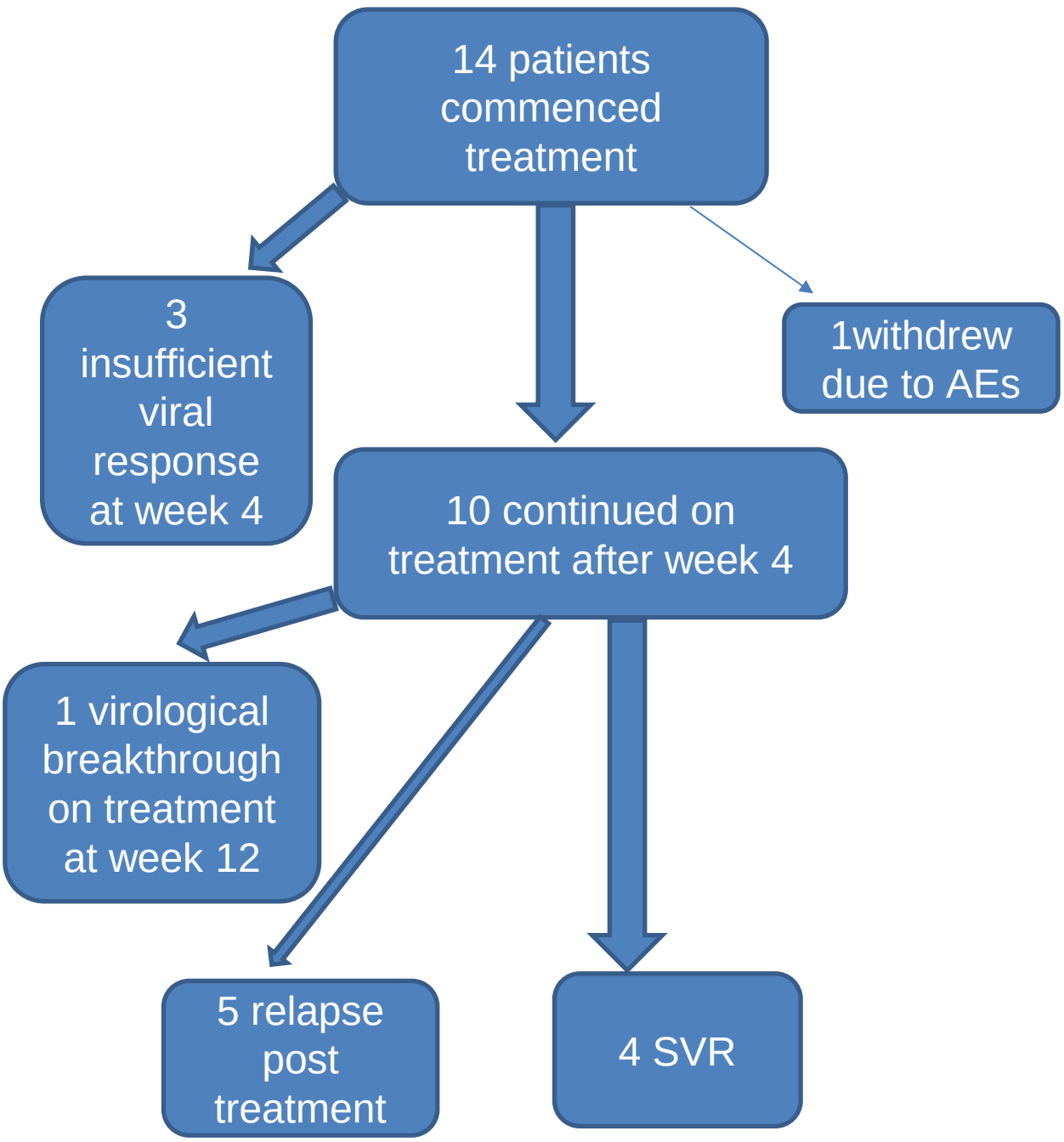
Schematic of Study Protocol with treatment stopping rules based on virological response and samples collected for in-vitro drug sensitivity phenotyping



Patient outcomes



Results by outcome of capture-fusion assay