

# The clinical effectiveness and cost-effectiveness of STeroids Or Pentoxifylline for Alcoholic Hepatitis (STOPAH): a 2 × 2 factorial randomised controlled trial

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**Declared competing interests of authors:** Mark Thursz has received fees for advisory boards and speaker engagements from Gilead, BMS, Abbvi, MSD, Jenssen and Abbott Laboratories. Paul Roderick has received grant support from Pfizer and is a member of the Health Services and Delivery Research Board. Michael Allison has received fees for advisory board engagements from Norgine and Luke Vale is a member of the Clinical Trials Board.

Published December 2015

DOI: 10.3310/hta191020

## Plain English summary

### The STOPAH trial

Health Technology Assessment 2015; Vol. 19: No. 102

DOI: 10.3310/hta191020

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# Plain English summary

## What was the problem?

Alcoholic hepatitis is an inflammatory condition of the liver caused by prolonged excessive alcohol consumption. Alcoholic hepatitis results in jaundice and liver failure; in the severe form of disease death may occur in 30% of patients within the first month. Previous clinical trials have failed to conclusively identify a treatment for this condition.

## What did we do?

This trial tested whether or not prednisolone or pentoxifylline (which suppress inflammation) reduced the number of deaths in patients with severe alcoholic hepatitis. Over 1100 patients in 65 hospitals were included.

## What did we find?

The number of deaths in the first month was reduced among patients taking prednisolone, but the effect was relatively weak and did not persist. Pentoxifylline did not appear to confer any benefit at any time. Patients treated with prednisolone had serious infections twice as frequently (13% vs. 7%) as in those who did not receive this drug. The trial showed that certain laboratory (prothrombin time and levels of bilirubin, creatinine and urea) and clinical (age and presence of encephalopathy) values helped predict a poor outcome of alcoholic hepatitis.

After 1 year, half the patients had died, 37% had stopped drinking alcohol and 20% attended an alcohol rehabilitation programme.

## What does this mean?

Prednisolone has a modest effect and could be used to treat alcoholic hepatitis. In the longer term, more effort needs to be made to get patients into rehabilitation programmes. New treatments are required to suppress the inflammation in the liver without increasing the risk of infection.



ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

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## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/14/44. The contractual start date was in July 2010. The draft report began editorial review in October 2014 and was accepted for publication in August 2015. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

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