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

Mark Thursz,$^1$* Ewan Forrest,$^2$ Paul Roderick,$^3$ Christopher Day,$^4$ Andrew Austin,$^5$ John O’Grady,$^6$ Stephen Ryder,$^7$ Michael Allison,$^8$ Dermot Gleeson,$^9$ Anne McCune,$^{10}$ David Patch,$^{11}$ Mark Wright,$^{12}$ Steven Masson,$^4$ Paul Richardson,$^{13}$ Luke Vale,$^{14}$ Jane Mellor,$^{15}$ Louise Stanton,$^{15}$ Megan Bowers,$^{15}$ Ian Ratcliffe,$^{15}$ Nichola Downs,$^{15}$ Scott Kirkman,$^{14}$ Tara Homer$^{14}$ and Laura Ternent$^{14}$

$^1$Department of Surgery and Cancer, Imperial College London, London, UK
$^2$Department of Gastroenterology, Glasgow Royal Infirmary, Glasgow, UK
$^3$Primary Care & Population Sciences, University of Southampton, Southampton, UK
$^4$Institute of Cellular Medicine, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK
$^5$Department of Gastroenterology, Derby Royal Hospital, Derby, UK
$^6$Institute of Liver Studies, King’s College Hospital, London, UK
$^7$Department of Hepatology, Nottingham University Hospitals NHS Trust and National Institute for Health Research Biomedical Research Unit, Queens Medical Centre, Nottingham, UK
$^8$Department of Hepatology, Addenbrookes Hospital, Cambridge, UK
$^9$Department of Hepatology, Sheffield Teaching Hospitals Foundation Trust, Sheffield, UK
$^{10}$Department of Hepatology, Bristol Royal Infirmary, Bristol, UK
$^{11}$Sheila Sherlock Liver Centre, Royal Free Hospital, London, UK
$^{12}$Department of Hepatology, University Hospital Southampton NHS Foundation Trust, Southampton, UK
$^{13}$Department of Hepatology, Royal Liverpool Hospital, Liverpool, UK
$^{14}$Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, UK
$^{15}$Southampton Clinical Trials Unit, University of Southampton, Southampton, UK

*Corresponding author
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Plain English summary

The STOPAH trial
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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.
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This report

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