HCV Research UK
and STOP-HCV

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HCV Research UK

- Consists of
  - A cohort of patients (target n = 10,000)
  - A database
  - A biobank
  - Written informed consent

- i.e. is not an end in itself but a resource for all to access
Locations of Recruitment Sites

Original 18
- Glasgow
- Aberdeen
- Dundee
- Edinburgh
- Newcastle upon Tyne
- Sheffield
- Nottingham
- Lincoln
- Derby
- Birmingham
- B’ham Children’s
- Leicester
- Cambridge
- Oxford
- London x3
- Plymouth

New Sites
- Manchester x2
- Liverpool
- Leeds
- Southampton
- Wycombe
- Middlesbrough
- Bradford
- Preston
- Blackburn
- Blackpool
- Blackpool
- Shrewsbury
- Birmingham Heartlands
- Sandwell & City
- Kings (adults & children)
- Leeds children
- Chelsea & Westminster
- Frimley / Royal Surrey
- St Marys children
- Monklands (Airdrie)
Patients Recruited Per Month

Total Recruitment by Month

- Total Actual by month
- Total Planned
- Total Actual (cumulative)

March 2012  Dec 2013  Oct 2014
HCV R UK cohort – current status

• 11530 “all-comers”
  • Includes children, multiple ethnicities, all liver disease status from spontaneously resolved infection through to liver transplant

• 567 (4.9%) listed as HIV positive

• 610 (5.3%) listed as taking anti-retrovirals (!)
HCV R UK targeted sub-studies: (i) Expanded Access Programme

• NHS England

• N = 806 patients with immediately life-threatening end-stage liver disease treating with all oral DAAs

• Overall SVR rate = 81%

• HIV co-infection recorded in 45 (5.6%)
HCV R UK targeted sub-studies: (ii) STOP-HCV Cirrhosis

• 1264 patients (recruitment closed), separate consent for annual clinical update including alcohol questionnaire and sampling

• Identification of host, viral and environmental factors associated with disease progression (decompensation, HCC)

• HIV co-infection recorded in 52 (4.1%)
HCV R UK targeted sub-studies: (iii) Real world DAA outcomes

• Target = 1200 patients receiving DAA-containing therapy since July 2015
• Compensated cirrhotics plus non-cirrhotics
• Currently n = 787
• HIV co-infection recorded in 50 (6.4%)
HCV R UK is a resource

- Applications for data and/or biological samples are made on-line to our Tissue and Data Access Committee
- TDAC is constituted as an LREC therefore ethical permission is agreed
- Cost recovery policy – amount depends on who is asking for what material for what purpose
- We clean data and fill data gaps by reference to the individual patients at each recruitment site
- Around 80 TDAC requests have been approved/completed thus far
STOP-HCV

• MRC Stratified Medicine Programme – STratified medicine to OPtimise therapy for patients with HCV infection

• Large consortium, 11 Universities, 7 Industry partners, 2 Wellcome Trust Institutions

• £5 million, start date Sept 2013 for 5 years
STOP-HCV: AIMS

• Effective stratification to develop **prognostic risk prediction models** to identify patients that will benefit from different treatment options, including DAAs

• Stratification within **gt3 infection**

• Stratification of patients with (i) established **cirrhosis**, and (ii) **HIV co-infection** to determine **treatment outcome** and **disease progression**
WS 1
HCV Research UK dbase + samples

WS 2 Viral genomics

WS 3 Host genomics

WS 4 Immune markers

WS 5 Biomarkers

WS 6
Integrative analysis

WS 7
Clinical algorithm development

+ Gilead sponsored BOSON study (n ≈ 600)
+ STOP-HCV1 trial (n ≈ 400)
STOP-HCV in Practice

• STOP-HCV Cirrhosis study (n=1264) and EAP (n=806)
  • Full-length NGS on all viraemic patients
  • Host genotyping via UK MRC Biobank chip
  • Biomarkers
• Link to disease progression and treatment outcome
• STOP-HCV is open for collaboration
  • Applications to the STOP-HCV Steering Committee
Acknowledgements

HCV Research UK

• Medical Research Foundation
• Management Group
  • John McLauchlan (Glasgow)
  • Will Irving (Nottingham)
  • Graham Foster (London)
  • Sharon Hutchinson (Glasgow)
  • John Dillon (Dundee)
  • Bryony Wilkes (Project manager)

STOP-HCV

• Medical Research Council
• Steering Committee
  • Ellie Barnes (Chair)
  • Emma Hudson (Project manager)
• Workstrand leaders
  • John McLauchlan, Peter Simmonds, Chris Spencer, Paul Klenerman, Will Irving, Chris Holmes, Graham Cooke
• Charles Gore (Hepatitis C Trust)
• Phil Troke (Gilead)