MRC Clinical Trials Unit | UCL

STOP-HCV Stratified Medicine for HepC

Attach Participant ID label

Form 03 - Randomisation
Version 4.0 01-Nov-2017

Visit Date: d d m m m y y y y

☞ **Enrolment must take place within 180 days of a Fibroscan or biopsy indicating mild disease and within 60 days of screening blood test results (except CD4+ cell count which must be within 1 year if HIV infected).**

☞ **Return completed CRFs by secure email to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817.**

☞ **If the participant is not eligible or will not be enrolled, please still submit this completed form.**

A. INCLUSION CRITERIA	**Yes**	**No**
☞ **All questions A1-A9 must be answered "yes" or "not applicable" for the participant to be eligible.**		
1a. Has the participant initialled all the mandatory boxes, ticked one of each optional box, and signed the informed written consent form?	☐	☐
b. What was the date of consent? d d m m m y y y y		
2. Aged ≥18 years	☐	☐
3. Infected with HCV genotype 1a or 1b or 4 with access to first-line treatment appropriate for their genotype (ombitasvir/paritaprevir/(dasabuvir)/ritonavir or glecaprevir/pibrentasvir)		
At least one detectable viremia 6 months prior to randomisation (by quantitative HCV RNA, qualitative assay or HCV genotype), with no intervening undetectable results	☐	☐
4. Plasma HCV RNA >LLOQ at screening	☐	☐
5. No evidence of significant liver fibrosis resulting from any aetiology (defined as Fibroscan score ≤7.1kPa, equivalent to F0-F1, within 180 days prior to randomisation, or biopsy consistent with mild fibrosis (Ishak score <=2/6) within 180 days prior to randomisation)	☐	☐
6. BMI >=18kg/m²	☐	☐
7. Laboratory tests: platelets >=60x10^9/L, haemoglobin >12g/dL (male) or >11g/dL (female), creatinine clearance (estimated using Cockcroft-Gault) >=60mL/min, international normalised ratio (INR) <1.5	☐	☐
8a. Screening HCV viral load <10,000,000IU/mL (less than 10 million IU/mL)	☐	☐
b. Date of HCV viral load result: d d m m m y y y y		
c. HCV viral load result (IU/mL): ☐☐ , ☐☐☐ , ☐☐☐		
d. Type of assay used: ☐ Cobas Amplicor v2 (Roche) ☐ Realtime HCV (Abbott) ☐ Aptima QuantDX (Hologic) ☐ Versant HCV assay v2 (Siemens) ☐ Other e. Please specify _____		
9. If HIV infected, is the participant on antiretroviral therapy with HIV viral load <50 copies/mL for >24 weeks at the screening visit? ☐ Not applicable	☐	☐

B. EXCLUSION CRITERIA	**Yes**	**No**
☞ **All questions B1-B13 must be answered "no" for the participant to be eligible.**		
1. Previous DAA exposure for this infection (previous treatment with pegylated-interferon and/or ribavirin allowed. DAA treatment for a previously cured infection allowed)	☐	☐
2. The patient is a woman who is lactating, or pregnant, or planning to become pregnant, or not willing to use effective contraception during the study and for 4 months after last dose of study medication	☐	☐
3. The patient is a woman currently taking ethinyl-oestradiol-containing medicinal products such as those contained in most combined oral contraceptives or contraceptive vaginal rings	☐	☐
4. The patient is a man who is planning pregnancy with a female partner, or not willing to use effective contraception during the study and for 7 months after last dose of study medication	☐	☐
5. Malignancy within 5 years prior to screening	☐	☐
6. Any condition in the judgement of the investigator which might limit the patient's life expectancy	☐	☐
7. Currently receiving medication known to interact with study medication (ombitasvir, paritaprevir, dasabuvir, ritonavir, sofosbuvir, ledipasvir, ribavirin, glecaprevir, pibrentasvir)	☐	☐
8. Disorder which may cause ongoing liver disease including, but not limited to, active hepatitis B, ongoing alcohol misuse	☐	☐
9. Any disorder which in the opinion of the investigator may have a significant negative impact on the ability of the patient to adhere to the trial regimen	☐	☐
10. Use of other investigational products within 60 days of screening	☐	☐
11. Known hypersensitivity to any active ingredient and/or excipients of the study medicines as listed in the protocol	☐	☐
12. History of severe pre-existing cardiac disease, including unstable or uncontrolled cardiac disease, in the previous six months	☐	☐
13. Haemoglobinopathies (e.g., thalassemia, sickle-cell anaemia)	☐	☐

C. OPTIONAL CONSENT ITEMS	**Yes**	**No**
☞ **Please record the participant's answers to the optional items on the consent form.**		
1. I agree that my GP can be told that I am taking part in this study and that my GP can be contacted about my wellbeing.	☐	☐
2. I agree to have the clinic test for the IL-28 gene, the clinic will inform me of the result when possible.	☐	☐
3. I agree that my stored blood samples can be used for human genetic testing relating to Hepatitis C infection. I understand that I will not be given the results of tests performed on stored samples. These samples will be securely stored with no names or identifiers other than my study number and initials for 30 years and may be sent and used for testing outside of the EU. After the 30 years all specimens will be destroyed.	☐	☐

D. ELIGIBILITY OUTCOME

1. Is the participant eligible for enrolment into the STOP-HCV-1 study? ☐ Yes ☐ No **If no, stop here, sign below and submit the form**

2a. Will the **eligible** participant be enrolled into the STOP-HCV-1 study? ☐ Yes ☐ No

b. If No, please specify why the participant will not be enrolled, sign below and submit the form: _____

_____

E. ON DAY OF RANDOMISATION (Day 0)

☞ **Please ensure Form 01 - Screening and Form 02 - Laboratory Results have been submitted.**

☞ **If the participant is a woman of childbearing potential, please ensure a negative urine pregnancy test has been done prior to randomisation.**

1a. When does the participant intend to take their first dose? d d m m m y y y y

b. Approximate time: h h : m m (use 24 clock)

2. What first-line treatment will the participant be prescribed?

☐ Viekirax (ombitasvir/paritaprevir/ritonavir) and Exviera (dasabuvir) with or without weight-based Ribavirin (genotype 1a/1b only)

☐ Viekirax (ombitasvir/paritaprevir/ritonavir) with or without weight-based Ribavirin (genotype 4 only)

☐ Maviret (glecaprevir/pibrentasvir) with or without weight-based Ribavirin (genotype 1a/1b and 4)

F. RANDOMISATION

☞ **Please call MRC CTU now to randomise the participant. You will need their NHS number.**

1. Which group has the participant been randomised to?

a. **Tick one**

☐ Fixed first line (56 days)

☐ Varying first line for b. ☐☐ days

c. **Tick one**

☐ With weight-based ribavirin

☐ Without weight-based ribavirin

2. Enrolment number: ☐☐☐

☞ **Following randomisation, please complete a prescription for first-line treatment and add prescribed drugs to Form 09 - Trial Drug Log.**

☞ **Please offer the participant a Diary card.**

☞ **If randomised on a Friday, please ensure the participant has site contact numbers.**

Signature:	Printed Name:	Date Completed: d d m m m y y y y

☞ *Please return by secure email to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817*

For office use only:

Date form received at CTU: dd - mmm - yyyy

Date form entered onto database : dd - mmm - yyyy

Initials of data enterer: ☐☐☐☐