ANRS C013 HEPAVIH - Inter-cohort and clinical centers collaboration of subjects co-infected by human immunodeficiency virus and hepatitis C

Head : Wittkop Linda, INSERM, U1219, Centre de Recherche Inserm Bordeaux Publique Health, équipe Morpheus, CMG-EC
Salmon Dominique, Services des Maladies Infectieuses et Tropicales
Sogni Philippe, Service d'Hépatologie

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<table>
<thead>
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<td>CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation</td>
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<th>General Aspects</th>
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| Medical area | Immunology
Infectious diseases |
| Health determinants | Lifestyle and behavior |
| Keywords | Adults, disease carriers, cured, treatment, co-infection |

<table>
<thead>
<tr>
<th>Collaborations</th>
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<tbody>
<tr>
<td>Participation in projects, networks and consortia</td>
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<table>
<thead>
<tr>
<th>Funding</th>
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<tbody>
<tr>
<td>Funding status</td>
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<th>Governance of the database</th>
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<p>| Sponsor(s) or organisation(s) | ANRS - AGENCE NATIONALE DE RECHERCHES SUR LE SIDA ET LES HEPATITES VIRALES |</p>
<table>
<thead>
<tr>
<th>Name of the director</th>
<th>Surname</th>
<th>Address</th>
<th>Phone</th>
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<tr>
<td>Wittkop</td>
<td>Linda</td>
<td>VIH, Hépatites Virales et comorbidités : épidémiologie clinique et santé publique / Multimorbidity and Public Health in Patients with HIV or Hepatitis (MORPH3Eus) CMG-EC de l’INSERM U1219 / ANRS Université de Bordeaux ISPED 146, rue Léo Saignat ? CS61292 33076 Bordeaux cedex FRANCE</td>
<td>+33 (0)5 57 57 13 92</td>
<td><a href="mailto:linda.wittkop@u-bordeaux.fr">linda.wittkop@u-bordeaux.fr</a></td>
</tr>
<tr>
<td>Salmon</td>
<td>Dominique</td>
<td>INSERM, U1219, Centre de Recherche Inserm Bordeaux Publique Health, équipe Morpheus, CMG-EC</td>
<td>+33 (0) 1 42 34 79 56</td>
<td><a href="mailto:dominique.salmon@aphp.fr">dominique.salmon@aphp.fr</a></td>
</tr>
<tr>
<td>Sogni</td>
<td>Philippe</td>
<td>Hôpital Cochin</td>
<td></td>
<td><a href="mailto:philippe.sogni@aphp.fr">philippe.sogni@aphp.fr</a></td>
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<tr>
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<td>Esterle</td>
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<tr>
<td><strong>Surname</strong></td>
<td>Laure</td>
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<tr>
<td><strong>Email</strong></td>
<td><a href="mailto:laure.esterle@u-bordeaux.fr">laure.esterle@u-bordeaux.fr</a></td>
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<tr>
<td><strong>Unit</strong></td>
<td>INSERM, U1219, Centre de Recherche Inserm Bordeaux Publique Health, équipe Morpheus, CMG-EC</td>
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<tr>
<td><strong>Address</strong></td>
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<td><strong>Unit</strong></td>
<td>Service de recherches fondamentales, cliniques et thérapeutiques sur les Hépatites virales</td>
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<td>Cohort study</td>
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<td><strong>Database recruitment is carried out by an intermediary</strong></td>
<td>A selection of health institutions and services</td>
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<td><strong>Database recruitment is carried out as part of an interventional study</strong></td>
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**Main objective**

**Short term:**
- Describe patient's characteristics
- Analyze factors associated to a treatment of hepatitis C: beginning of the treatment, continuation or stop of the treatment.
- Validate the field performance of not-invasive markers of hepatic fibrosis.

**Mid-term:**
- Realize an observational study of the evolution of hepatitis during an anti-VHC treatment, in an antiviral situation
- Study the clinical and biological tolerance to the different treatments.
- Study the impact of the observance of the treatment anti HIV and the life quality of patients.

**Long term:**
Study the natural history of chronic hepatitis, in particular at the stage of cirrhosis.
- Analyze the factors associated to the evolution to fibrosis, to a decompensated hepatic disease or a hepatocellular carcinoma.
- Evaluate the effects of antiretroviral agents on the evolution of not-treated hepatitis
- Study the potential interactions between different virus of hepatitis

**Inclusion criteria**

Adults infected by HIV virus carriers of VHC or cured after anti-VHC treatment, or spontaneously healed without anti-VHC treatment or benefiting from an anti-VHC tritherapies.

**Population type**

- **Age**
  - Adulthood (19 to 24 years)
  - Adulthood (25 to 44 years)
  - Adulthood (45 to 64 years)
  - Elderly (65 to 79 years)

- **Population covered**
  - Sick population

- **Pathology**
  - B24 - Unspecified human immunodeficiency virus [HIV] disease
  - B15-B19 - Viral hepatitis

- **Gender**
  - Male
  - Woman
  - Other

- **Geography area**
  - National

- **Detail of the geography area**
  - French multi-centers cohort (28 centers)

**Database objective**

**Dates and inclusions duration:** Phase 1: 2005-2008 (3 years) Phase 2: 2011-2014 (3 years)
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<td>Current data collection</td>
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<td><strong>Type of data collected</strong></td>
<td>Clinical data, Declarative data, Paraclinical data, Biological data</td>
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<td><strong>Clinical data (detail)</strong></td>
<td>Direct physical measures, Medical registration</td>
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<td><strong>Details of collected clinical data</strong></td>
<td>Clinical examination at inclusion and during the follow-up. Information collected during the clinical examination: weigh, height, waist and hips circumference</td>
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<td><strong>Declarative data (detail)</strong></td>
<td>Paper self-questionnaire, Face to face interview</td>
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<tr>
<td><strong>Paraclinical data (detail)</strong></td>
<td>Radiology, evaluation of the hepatic fibrosis</td>
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<tr>
<td><strong>Biological data (detail)</strong></td>
<td>Blood check</td>
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<td><strong>Presence of a biobank</strong></td>
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<td>Whole blood, Serum, Plasma</td>
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<td><strong>Details of biobank content</strong></td>
<td>Serum bank, plasma bank, DNA bank, total blood, tissues bank in a non-systematic way</td>
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</table>
| Health parameters studied          | Health care consumption and services  
|                                  | Quality of life/health perception  |
| Care consumption (detail)        | Medical/paramedical consultation  
|                                  | Medicines consumption  |
| Data collection method           | ---  |
| Classifications used             | Data utilization possible for academic teams and for industrials. Temporary access condition: project accepted by the scientific committee  |
| Quality procedure(s) used        | Yes  |
| Participant monitoring           | Monitoring by contact with the referring doctor  |
| Monitoring procedures            | Annual or bi-annual, specific according to the anti-VHC treatment  |
| Details on monitoring of participants | No  |
| Links to administrative sources  |  |

### Promotion and access

| Promotion |  |
|-----------|  |
| Link to the document | List of publications COHORTE ANRS CO13 HEPAVIH 20180830.pdf  |
| Description | List of publications in HAL  |
| Link to the document | http://www.ncbi.nlm.nih.gov/pubmed/?term=HEPAVIH+OR+ANRS+CO13+OR+%28cohere+AND+%28hiv+OR+AIDS%29  |
| Description | List of publications in Pubmed  |

### Access

<p>| Access |  |
|--------|  |
| Presence of document that lists variables and coding procedures | Yes  |
| Terms of data access (charter for data provision, format of data) | Data utilization possible for academic teams and for industrials. Temporary access condition: project accepted by the scientific committee  |</p>
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<tr>
<td>Access to individual data</td>
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