BHIVA Workshop 2015

David Chadwick
Why Do Research?

- Provides new information on best treatments, tests etc.
- Patient participation in research is beneficial for patients
- Doctors’/other HCW’s involvement in research improves standards of patient care.
- Brings in additional funding/staff to Departments
- Improves the prestige of Departments & Trusts
- Important for junior doctor/specialist nurse training
- It’s exciting/interesting!
Reasons not to do research

• Because we don’t have the time
• Because clinical services take precedent
• Because it is difficult and involves a lot of paperwork
• Because we’re not very good at it
• Because we might have to take a cut in salary (whilst training)
• Because research governance issues seem to make it virtually impossible
• Because we’re isolated, unloved and unsupported
• Because we don’t want to help someone else who is going to get all the glory
• Because the NHS and other funding bodies only ever give funding to the “best” R&D centres
Best Research for Best Health: A New National Health Research Strategy

The NHS contribution to health research in England: a consultation
NIHR Local Clinical Research Networks (LCRNS) from 2013
NIHR-IDM Specialty Group: Some facts and figures

- Specialty groups have been operating in ? areas of UK since 2006/7 (CLRNs/LCRNs)
- NIHR provides significant funding (PAs, other salaries) to research-active units
- ID-Microbiology Group includes GUM and public health research as well
- In 2013/14, nearly 30,000 patients were recruited into NIHR IDM studies
- Currently there are 195 active (currently recruiting or in set-up) IDM studies on the NIHR portfolio
- 39 of these studies are HIV studies, of which 17 are interventional (mainly RCTs) and 22 observational studies
- Well-known examples of recent HIV portfolio studies are PIVOT (RCT) and UKCHIC (observational)
Protease Inhibitor monotherapy Versus Ongoing Triple-therapy in the long term management of HIV infection
Consort Diagram

Patients assessed: n=695

Randomised: n=587

Excluded: n=108
- 30 previous ART change due to unsatisfactory VL response
- 28 VL ≥50 copies/ml at screening or last 24 weeks
- 19 did not return after screening
- 8 not on 2 NRTIs+NNRTI/PI regimen
- 26 had other reasons

Allocated to Ongoing Triple Therapy: n=291
- Started PIm during follow up: n=12

- Died before end of trial follow-up: n=1
  Complete withdrawal or lost to follow-up: n=11

Allocated to PI Monotherapy: n=296
- Did not receive allocated therapy: n=6
  - 4 patient decision
  - 2 adverse event after switch from NNRTI to PI & never stopped NRTIs

- Died before end of trial follow-up: n=6
  Complete withdrawal or lost to follow-up: n=5

Included in primary analysis: n=291

Included in primary analysis: n=296
Target and Actual Accrual and sites open for PIVOT

MHRA approval: March 2008
The PIVOT network

43 sites
The largest UK lead HIV treatment trial ever...
PIVOT in the context of other HIV MRC trials

PIVOT:
Best recruiting UK HIV treatment trial in 20 years!
Largest UK-only HIV treatment trial ever done by MRC!

<table>
<thead>
<tr>
<th>Study</th>
<th>Total recruitment</th>
<th>UK recruitment</th>
<th>Recruitment</th>
<th>Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONCORDE</td>
<td>1,760</td>
<td>829</td>
<td>Oct-88</td>
<td>Nov-91</td>
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<tr>
<td>ALPHA</td>
<td>1,305</td>
<td>406</td>
<td>May-90</td>
<td>Oct-91</td>
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<tr>
<td>DELTA</td>
<td>3,308</td>
<td>774</td>
<td>Mar-92</td>
<td>May-94</td>
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<tr>
<td>QUATTRO</td>
<td>100</td>
<td>100</td>
<td>Aug-95</td>
<td>Jul-96</td>
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<tr>
<td>ADHOC</td>
<td>167</td>
<td>128</td>
<td>Jul-97</td>
<td>Jun-99</td>
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<tr>
<td>INITIO</td>
<td>915</td>
<td>77</td>
<td>Feb-99</td>
<td>Apr-02</td>
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<tr>
<td>FORTE</td>
<td>142</td>
<td>142</td>
<td>Oct-99</td>
<td>Jul-02</td>
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<tr>
<td>ESPRIT</td>
<td>4,150</td>
<td>332</td>
<td>Mar-00</td>
<td>May-03</td>
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<tr>
<td>TILT</td>
<td>86</td>
<td>33</td>
<td>Mar-01</td>
<td>Jul-04</td>
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<tr>
<td>SMART</td>
<td>5,472</td>
<td>214</td>
<td>Jan-02</td>
<td>Jan-06</td>
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<tr>
<td>SPARTAC</td>
<td>371</td>
<td>125</td>
<td>Aug-03</td>
<td>Jul-07</td>
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<tr>
<td>STALWART</td>
<td>267</td>
<td>28</td>
<td>Sep-05</td>
<td>Jun-08</td>
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<tr>
<td>PIVOT</td>
<td>590</td>
<td>590</td>
<td>Nov-08</td>
<td>Jul-10</td>
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</table>

Note: SPARTAC was been published in 2013 and STALWART in 2010.
Welcome to the UK Clinical Research Network Study Portfolio

UKCRN Study Portfolio > InfectiousDiseases

A User Guide to this new version of the UKCRN Portfolio Search tool is available here.

Portfolios of Individual Countries:

New studies

Recently Added InfectiousDiseases studies
Summary list of studies added recently but with incomplete data.

Recently Released InfectiousDiseases studies
Full study records added in the last month.

Search for a study

Specialty: InfectiousDiseases
Specialty Group: All
Title / Acronym: hiv

Chief Investigator / Study Coordinator:
ISRCTN:
UKCRN Study ID:
Research Summary:

Find

Export to Excel

Study Status

<table>
<thead>
<tr>
<th>Specialty Group</th>
<th>In set-up</th>
<th>Recruiting</th>
<th>Closed / Suspended</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>ISRCTN</td>
<td>Acronym &amp; Title</td>
<td>Status</td>
<td>Type</td>
<td>Open to additional sites</td>
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<td>---------</td>
<td>--------------------------------------------------------------------------------</td>
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<tr>
<td>63267760</td>
<td><strong>Positive Voices: National Survey of People with HIV</strong> - Development and Implementation of Positive Voices: the National Survey of People Living with HIV</td>
<td>Suspended</td>
<td>Interventional and Observational</td>
<td>No</td>
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<tr>
<td></td>
<td><strong>AALPHI</strong> - Adolescents and Adults Living with Perinatal HIV cohort</td>
<td>Open</td>
<td>Observational</td>
<td>Yes, within lead country only</td>
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<tr>
<td></td>
<td><strong>aMASE</strong> - European network of HIV/AIDS Cohort studies to coordinate at European and international level clinical research on HIV/AIDS: advancing Migrant Access to health Services in Europe (EuroCoord: aMASE)</td>
<td>Open</td>
<td>Observational</td>
<td>No</td>
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<tr>
<td></td>
<td><strong>Attitudes to and Understanding of Risk of Acquisition of HIV (AURAH)</strong> - A cross-sectional questionnaire study of sexual risk behaviour, attitudes to HIV transmission, anti-retroviral treatment for prevention and wellbeing in HIV-negative individuals at risk of HIV-infection (recruited from sexual health clinics) to compare to a similar study that has been undertaken in HIV-positive individuals.</td>
<td>Open</td>
<td>Observational</td>
<td>No</td>
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<tr>
<td>32090191</td>
<td><strong>Best Foods For your heart</strong> - A randomised controlled pilot study to assess the feasibility of the Ultimate Cholesterol Lowering Plan dietary intervention for cardiovascular risk reduction in HIV dyslipidaemia</td>
<td>Open</td>
<td>Interventional</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td><strong>CCRN 3179 (HIV)</strong> - A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted</td>
<td>Open</td>
<td>Interventional</td>
<td>No</td>
</tr>
</tbody>
</table>
AALPHI
Adolescents and Adults Living with Perinatal HIV cohort

Specialty
Children (co-adopted by Infectious Diseases)

Portfolio Eligibility
Adopted non-commercial study

Research Summary

Study Type
Observational

Design Type
Not specified

Disease(s)
Infectious diseases and microbiology
All Diseases

Phase
N/A

Current Status
Open

Closure Date
05/07/2017

Global Sample Size
700

Global Recruitment to Date
45%

Geographical Scope
UK Multi-Centre

Lead Country
England

Open to new sites
Yes, within lead country only

Main Inclusion Criteria
To be added

Main Exclusion Criteria
To be added

Chief Investigator(s)
Dr Ali Judd

Further details, please contact
Dr Ali Judd