



Partner Study

Investigator meeting in Glasgow
8th November 2010

Agenda

- Welcome
- Study up date
- Recruitment
 - Panel discussion
- HIV test
- Update on data on transmission from serodifferent couple studies



Welcome

Alison Rodger



Study overview

Funded by: The National Institute of Health Research (NIHR) in England

Sponsored by: UCL – University College London

Conducted by: UCL and CHIP - Copenhagen HIV programme



Participating centres

1. Prof. Jürgen Rockstroch, Bonn
2. Dr. Jan Van Lunzen, Hamburg
3. Prof. Bogner, Munich
4. Dr. Brockmeyer, Bochum
5. Dr. Färkenhauer, Cologne
6. Dr. Christoph Stefan, Frankfurt
7. Dr. Kzmarie, Berlin
8. Dr. Lars Mathiesen, Copenhagen
9. Dr. Lars Ostergaard, Århus
10. Dr. Svend Sienewang, Odense
11. Prof. Jan Gerstoft, Copenhagen
12. Prof. Jose Gatell, Barcelona
13. Dr. Vincente Estrada, Madrid
14. Dr. Del Romero, Barcelona
15. Dr. Coll, Badalona
16. Dr. M Peña, Madrid
17. Dr. Gonzalez-Lahoz, Madrid
18. Dr. Antonio Antela, Compostela
19. Dr. Pompeyo Viciano, Seville
20. Dr. Miguel Gorgolas, Madrid
21. Dr. Angela Camacho, Cordoba
22. Dr. Felix Gutiérrez, Elche
23. Prof. Antonella d'Arminio Monforte, Milan
24. Dr. Mussini, Modena
25. Dr. Anders Sonnerburg, Stockholm
26. Dr. Anders Blachula, Stockholm
27. Prof. Brian Gazzard/David Ashoe, London
28. Prof. Jane Anderson, London
29. Dr. Jonathan Ainsworth, London
30. Dr. Sarah Filder, UK
31. Dr. Sir Allan, Birmingham
32. Dr. David White, Birmingham
33. Dr. Leen, Scotland
34. Dr. Alison Rodger, London
35. Dr. Post, London
36. Dr. Gompels, Birmingham
37. Dr. Richard Gibson, London
38. Dr. Martin Fischer, Brighton
39. Dr. Julie Fox, London
40. Dr. Okike, London
41. Dr. Ed Wilkins, UK
42. Dr. Palfreeman, Leicester
43. Dr. Freedman, Cardiff
44. Dr. O'Connell, London
45. Dr. Stoeckle, Basel
46. Prof. Weber, Zurich
47. Dr. Pietro Vernazza, St.Gallen
48. Dr. Enzo Benasconi, Lugano
49. Dr. Vanhems, Lyon
50. Dr. Pradier, Nice
51. Dr. Eiel, France
52. Prof. Pelloux, Paris
53. Prof. Clumeck, Belgium
54. Dr. Gráinne Courtney, Ireland
55. Dr. Amin Rieger, Austria
56. Dr. Hass, Austria
57. Prof. Jan. Prins, NL
58. Dr. Ristola, Finland
59. Dr. Antunes, Portugal



National Coordinators

Dr Amin Rieger,
Prof Nathan Clumeck,
Dr Lars Mathiesen,
Dr Matti Ristola,
Dr Christian Pradier,
Dr Jan Van Lunzen,
Dr Gráinne Courtney,
Prof Antonella d'Arminio Monforte,
Prof Francisco Antunes,
Dr Vincente Estrada,
Dr Katarina Westling,
Prof Pietro Vernazza,
Prof JM Prins,
Dr Alison Rodger,

Austria
Belgium
Denmark
Finland
France
Germany
Ireland
Italy
Portugal
Spain
Sweden
Switzerland
The Netherlands
UK



Executive members

- Prof Andrew Phillips, University College London (UCL)
- Prof Jens Lundgren, University of Copenhagen and Rigshospitalet, Copenhagen, Denmark
- Dr Alison Rodger, UCL
- Simon Collins, HIV i-Base, London
- Dr. Pietro Vernazza, Switzerland
- Dr. Vicente Estrada, Spain
- Dr. Jan Van Lunzen, Germany
- Tina Bruun, Copenhagen HIV Programme (CHIP)



Timeline

February 2011

- All sites operational and enrolling partnerships

September 2011

- All 1650 partnerships recruited

Late Summer 2013

- All partnerships followed for 2 years



Study overview

Tina Bruun



Ethical Approval Update

Countries with ethical approval in all centres

- The Netherlands, Denmark, Ireland, UK, Sweden and Finland.

Countries with ethical approval in some centres:

- Switzerland, Germany, Spain

Countries waiting for ethical approval

- Belgium, France, Portugal, Italy and Austria



Study update

- **16 sites are open and can enroll**
These sites are: 2 in Sweden, 4 in Denmark, 2 in Switzerland, 1 in Germany, 1 in Netherlands, 5 in UK, 1 in Ireland
- **9 partnerships enrolled:**
1 Netherlands, 3 Denmark, 3 Sweden, 1 UK and 1 Switzerland



Recruitment

Tina Bruun



Recruitment strategies:

1. Partnerships are recruited through their regular visit to the sites
2. Partnership identified by the clinic are approached by phone/letter and invited to participate in the study
3. The study is announced in the community and partnerships then refer themselves to clinic



Recruitment scenario example

Centre recruitment: 40 pairs

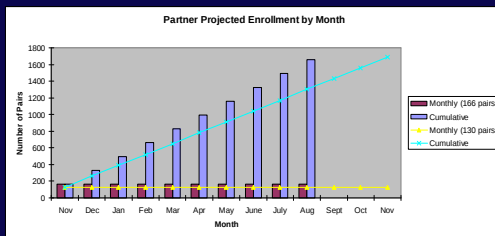
- If we assume 5-10% of patients eligible
- If centre screens 20/week: 2 likely eligible: 1 will enroll

If you recruit 5/month = 1.1/week

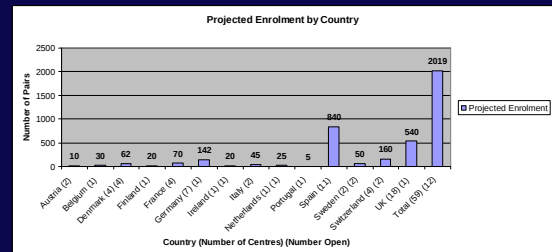
You'll recruit 40 pairs in **8 months**.

If you recruit 3.6/month = .8/week:

You'll recruit 40 pairs in **11 months**.

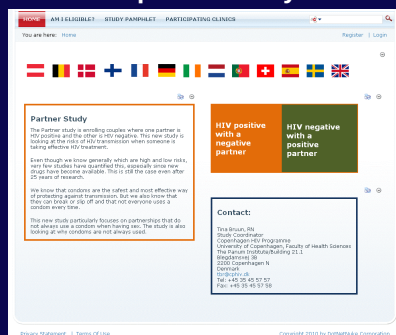


The graphs shows steady recruitment at 166 pairs/month and at 130 pairs/month. With only a slight reduction in recruitment (36 pairs less/month) we will need to extend by 3 months.



PARTNER: Website for study participants

www.partnerstudy.eu



Panel discussion on recruitment

Jens Lundgren

- Panel participants

- Anders Blaxhult, Sweden
- Lene Pors Jensen, Denmark
- Antonio Antela, Spain
- Michael Brady, UK



HIV test

Andrew Phillips



Transmission of HIV in serodifferent couple studies

An update

Alison Rodger



Systematic Review and Meta-analysis of Sexual Transmission of HIV

Attia et al (AIDS 2009)

- 11 cohorts reporting on 5021 heterosexual couples
- 461 transmission events
- Index not on ART
 - 998 PY follow up in 10 studies
 - 456 transmission events
 - Rate of HIV transmission per 100 PY 5.64 (3.28, 9.70)
- Index on ART
 - 1098 PY follow up in 5 studies
 - 5 transmission events
 - Rate of HIV transmission per 100 PY 0.46 (0.19, 1.09)
- Index on ART with VL<400 copies
 - 291 PY follow up in 2 studies
 - 0 events
 - Rate of HIV transmission per 100 PY 0 (0, 1.27)
 - Compatible with 1 transmission per 79 person years
- 92% reduction in transmissions with ART
- Greater precision required, no data identified for MSM



Serodifferent couple studies (I)

del Romero et al (BMJ 2010)

- Setting: Madrid (1989-2008).
- Heterosexual couples attending serodifferent couple clinic
- Index partner male (83%), IDU in index case (80%)
- HIV negative partner tested at baseline and at least once during follow up
- VL limit <500 copies (pre'99), <50 copies (post '99)
- 6/12 recall of risk behaviours



del Romero et al (BMJ 2010)

Index not on ART (341 couples)

- 11,000 risky sexual exposures, 863 PY follow up
- 5 HIV transmissions
- HIV transmission rate per 100 PY: 0.6 (0.2, 1.4)
- HIV transmission rate per 1000 unprotected contacts: 0.4 (0.1, 1.0)

Index on cART (149 couples)

- 7,400 risky sexual exposures, 417 PY follow up
- 92% HIV VL undetectable
- 0 HIV transmissions
- HIV transmission rate per 100 PY: 0 (0, 1.1)
- HIV transmission rate per 1000 unprotected contacts: 0 (0, 0.5)



Serodifferent couple studies (II)

Donnel et al (Partners in Prevention Study Team, Lancet, 2010)

- Setting: 7 SSA countries (2004-2007)
- 3381 heterosexual couples
- Index seropositive for HIV and HSV-2
- Couples followed for 24 months
- HIV testing:
 - HIV +ve partner: HIV VL baseline, 3,6,12 and 24 months
 - HIV -ve partner: 3 monthly HIV testing
 - Phylogenetic linkage of HIV transmissions



Donnel et al (Partners in Prevention Study Team, Lancet, 2010)

Not on ART

- 4558 PY
- 102 HIV linked transmissions
- HIV transmission rate per 100 PY: 2.24 (1.84, 2.72)

Initiated cART

- 273 PY
- 1 HIV linked transmission (<4/12 after ART started)
- HIV transmission rate per 100 PY: 0.37 (0.09, 2.04)

Low rate of transmission after cART initiation



Serodifferent couple studies (III)

Wang et al (JAIDS, 2010)

- Setting: Henin Province China (2006-2008).
- 1927 heterosexual couples
- HIV testing:
 - HIV positive partner: No HIV VL data
 - HIV negative partner: 6/12 HIV testing
 - No phylogenetic linkage of HIV transmissions
- 80.4% of index cases were on ART



Wang et al (JAIDS, 2010)

- 84 seroconversions in 1927 couples (4918 PY follow up)
- HIV transmission rate per 100 PY: 1.17
- No statistical significant difference in seroconversions between spouse on ART (4.8%) and not on ART (3.2%) ($p=0.12$)
- Not using condoms (RR 8.42 [4.8, 14.6]) and increased frequency sexual activity (5.13 [2.76, 9.5]) associated with transmission
- No data on adherence (previous studies 66% poor adherence)
- No data on HIV VL of index case (previous studies 50% failure rate by 5 years)



Conclusions

- ART reduces heterosexual transmission of HIV
- More precise estimates required
- Ongoing studies include HPTN 052 - RCT in 1750 heterosexual couples followed for 60 months - and PARTNER
- Virtually no data currently available for transmission risks through insertive and receptive anal intercourse when HIV VL suppressed.

