



Minutes of Investigator Meeting

Thursday 17th October 2013, EACS, Brussels, Belgium

Meeting leader: Tina Bruun

Participants: 18 investigators and 6 CHIP staff members

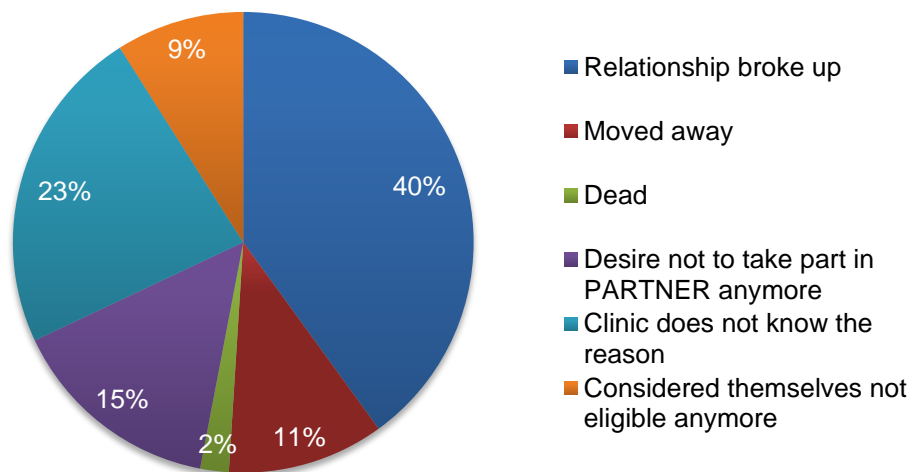
Welcome

Tina welcomed and reviewed the agenda.

Status of PARTNER

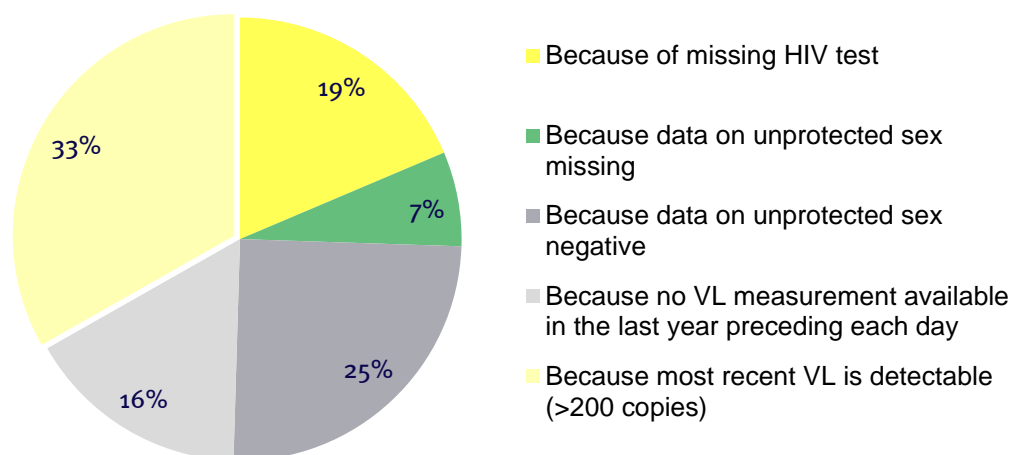
Since start in September 2010 monthly enrolment peaked after 6 to 8 months with almost 60 couples per months and has since levelled off to around enrolment of 20-25 couples a months. Currently 1109 couples of the aim of 1374 are enrolled. Enrolment is now slow as the pool of eligible partnerships at sites in many cases has dried out.

Reasons for leaving the study were reviewed:



Quite a number of couples are currently leaving the study since they do not want to continue after the protocol defined primary study period of two years. Couples are encouraged to remain in the study, but we naturally respect their wish to leave after two year.

Not all calendar time of follow-up can be included in the primary analysis since the protocol requirement of HIV-test and VL testing within the window period reduces the time counted for the primary endpoint – currently 87% of follow-up time is included, reasons for not including follow-up time are distributed as follows:



Payment follows the above requirements, so for a complete follow-up year to be reimbursed (with 180€) it is required to have:

- 2 follow up questionnaires from the HIV-negative partner
- 2 follow up questionnaires from the HIV-positive partner
- 2 eCRF from the positive partner
- 2 eCRF from the negative partner
- 1 HIV test
- One VL

Follow up of Heterosexual couples

Tina emphasised that it is important to have the heterosexual couples in for a final visit before the end of March – it is an advantage to wait as long as possible to have accumulated as much follow-up time as possible.

Participants becoming HIV-positive

Jens emphasised the importance of collecting blood samples from both participants in the couples to be able to identify possible linked HIV transmission

Update on PARTNER phase 2

Jens reviewed the lack of discordant homosexual couple follow-up time in other studies including HPTN052, thus underlining that the PARTNER is the only study to establish documentation on the risk in homosexuals.

PYFU receptive anal sex with ejaculation	Unknown	282	726
upper 95% confidence limit for Risk of transmission – overall	If no transmissions occur in the study: 1/54 couple years combined	If no transmissions occur in the study(**): 1/474 couple years combined	If no transmissions occur in the study(**): 1/847 couple years combined
upper 95% confidence limit for Risk of transmission – anal sex	If no transmissions occur in the study: 1/14 couple years anal sex	If no transmissions occur in the study (**): 1/238 couple years anal sex	If no transmissions occur in the study (**): 1/610 couple years anal sex

* Eligibility criteria: HIV negative reporting condom-less sex; HIV+ VL<200 in the last year

** These numbers will be lower if one or more linked transmissions are observed (see table 1 above for details)

The above table is from a manuscript prepared by Alison – the manuscript will be circulated to investigators.

Funding

Fundraising is ongoing, we receive 67,000€ from Augustinusfonden a Danish foundation and 200,000€ from pharma industry of the total budget of 653,000€. Investigators are encouraged to look for possibilities of national funding of follow-up time for the couples in their country.

Giulio from the Italy and member of the PARTNER Executive Committee site emphasised the importance of study for the community and especially the gay community. We need to once for all to document the risk of transmission in discordant couples practicing condomless sex.

David White from UK proposed to establish a website for community to donate small amounts (or large) to help funding part 2 of the study.

Minutes: Jesper Grarup