

DAD Newsletter

February 2012



Welcome to the latest update on the progress of the D:A:D Study. This newsletter includes information that is critical for the maintenance of the high quality that the D:A:D Study is known for. Please disseminate this newsletter to all persons involved with the study.

General information

After the final cleaning and enrolment of cohort III, a total of 49,734 HIV positive persons have contributed to prospective follow-up in the D:A:D study. Over the 12 years that the study has been running, almost 4,000 people have died, and we have confirmed reports of 770 MIs, 520 strokes and 700 non-AIDS-defining malignancies. Approximately 80 people are known to have progressed to end-stage renal disease and 1340 developed diabetes.

Funding

The D:A:D study has been funded for an additional year of follow-up until end of January 2013. Over the months to come the D:A:D Steering Committee (SC) will submit a report to the EMA that will form the basis of discussions later in the year on the unresolved research questions relating to ARV drug safety that will continue to be studied in D:AD beyond January 2013. We will update you on our progress as soon as possible.

Event Case Report Forms (CRFs)

The high quality of completion of these CRFs is a critical component of the continued success of the D:A:D Study. Thanks to all colleagues that continue to contribute to this effort. As you may know, after carefully reviewing the information submitted, staff at the Coordinating Centre (CC)

RECENT PUBLICATIONS:

1. Elevated triglycerides and risk of MI in HIV-positive persons , the DAD study.

SW Worm, DA Kamara, P Reiss, O Kirk, W El-Sadr, C Fux, E Fontas, A Phillips, AD Monforte, S De Wit, K Petoumenos, N Friis-Møller, P Mercie, J Lundgren, C Sabin. AIDS 2011 May 30

2. The impact of fasting on the interpretation of triglyceride levels for predicting myocardial infarction risk in HIV-positive individuals: The D:AD Study.

DA Kamara, S Worm, P Reiss, M Rickenbach, A Phillips, O Kirk, AD Monforte, M Bruyand, M Law, S De Wit, C Smith, C Pradier, JD Lundgren, C Sabin. JID 2011 Aug

3. Evaluation of sudden death and non-hemorrhagic stroke and the association with HIV protease inhibitor (PI) usage.

may ask the site for clarification about the event and then classify the event according to standard algorithms. We are aware that HgbA1C is increasingly being used to make a diagnosis of diabetes, and we will shortly revise the relevant study documents to reflect this.

For the continued success of the study, it remains critical that all the incident cases of the study endpoints are reported in a timely and detailed manner. We encourage the sites to continue to closely follow patients involved in D:A:D and to promptly report all relevant cases to the CC.

Upcoming deadlines, event query and merger 13

During Spring all cohorts will receive a list of pending events including:

- Events not yet reported
- Events with outstanding/incomplete source data
- Events with a date discrepancy

Please send all outstanding events to the D:A:D CC before 25 March 2012.

The data submission deadline for Merger 13 is 1st June 2012.

D:A:D SC Meeting

The next D:A:D SC face-to-face meeting will be held 6 March 2012 at CROI in Seattle.

S Worm, DA Kamara, E Fontas, S De Wit, W El-Sadr, AD Monforte, M Law, A Phillips, L Ryom, F Dabis, R Weber, C Sabin, JD Lundgren, on behalf of the DAD study group. JID 2012 Jan.

[Link to publications](#)

SUBMITTED ARTICLES:

1. Antiretroviral drug-related liver mortality is low in the absence of HBV or HCV coinfection: The D:A:D study.

H Kovari, C Sabin, B Ledergerber, L Ryom, S Worm, C Smith, A Phillips, P Reiss, E Fontas, K Petoumenos, S De Wit, P Morlat, JD Lundgren and R Weber.

2. Incidence and characteristics of non-AIDS-defining malignancies (NADM) in the combination antiretroviral therapy (cART) era: the D:A:D Study.

SW Worm, M Bruyand, P Reiss, E Fontas, O Kirk, A Phillips, H Furrer, AD Monforte, S De Wit, M Law, JD Lundgren, C Sabin.

3. Predicting the short term risk of diabetes in HIV positive patients: The Data Collection on Adverse events of Anti-HIV Drugs (D:A:D Study).

K Petoumenos, S Worm, E Fontas, R Weber, S De Wit, M Bruyand, P

Reiss, W El-Sadr, AD Monforte, N
Friis-Møller, LD Lundgren, M Law on
behalf of the D:A:D Study Group.

RECENT PRESENTATIONS:

**13th International Workshop on
Adverse Drug Reaction and co-
morbidities in HIV, Rome, July
2011: Development of a definition
for for Rapid Progression (RP) of
renal disease in HIV-positive**

persons. L Ryom, DA Kamara, S
Worm, MJ Ross, P Reiss, CA Fux, P
Morlat, O Moranne, O Kirk, C Smith
and JD Lundgren for the D:A:D Study
Group (Oral)

**13th European AIDS
Conference/EACS, Belgrade,
October 2011: Non-AIDS defining
malignancies (NADM) in the D:A:D
study: Time trends and predictors
of survival** SW Worm, C Sabin, P
Reiss, M Law, F Bonnet, E Fontas, M
Rickenbach, A D'Arminio Monforte, A
Phillips, O Kirk, S De Wit and J D
Lundgren (Oral)

**15th IWHOD, Prague 2011:
Cancer or not collection and
preliminary assessment of NADM in
the D:A:D study**

S. Worm, J Tverland, M Bruyand, P
Reiss, E Fontas, W El-Sadr, O Kirk, R
Weber, A d'Arminio Monforte, S De

Wit, L Ryom, N Friis-Møller, M Law,
JD Lundgren and C Sabin (Poster)

**How to identify patients enrolled in
multiple cohorts, exemplified by the
D:A:D study**

J. Kjær, M.M.J. Hillebregt, R.S. Brandt
, E. Fontas , E. Balestre, H. McManus,
I. Fanti, M. Delforge and M.
Rickenbach for the D:A:D Study
Group (Poster)

**Improving data quality in HIV
cohort collaborations - exemplified
by the D:A:D study**

R.S. Brandt, M. Rickenbach, M.M.J.
Hillebregt, E. Fontas , S. Geffard, H.
McManus, I. Fanti , M. Delforge , B
Ledergerber and J. Kjær for the D:A:D
Study Group (Poster)

**16th IWHOD Athens 2012:
The importance of well validated
outcomes when assessing the
association between the latest CD4
count and the risk of stroke**

C. Sabin et al. (Oral)

**Fasting and non-fasting cholesterol
and risk of myocardial infarction
(MI): The D:A:D study**

DA. Kamara et al. (Poster)

**CROI 2012 Seattle:
Non-AIDS defining malignancies**

(NADMs) and immunosuppression:

The D:A:D study

S Worm et al. (Oral)

Associations between markers of immunosuppression and the risk of cardiovascular (CV) disease: The D:A:D study

C. Sabin et al. (Poster)

Atazanavir (ATV)- containing antiretroviral treatment is not associated with an increased risk of cardio- or cerebro-vascular events (CVE) in the D:A:D study

A. d'Arminio Monforte et al. (Poster)

Exposure to antiretrovirals (ARVs) and the risk of renal impairment among HIV+ persons with normal baseline renal function: the D:A:D study

L. Ryom et al. (Poster)

[Link to presentations](#)