

Dear DAWN-plasma investigators,
Dear friends and colleagues,

We hope you and your family are safe and healthy, and also that you and your collaborators are able to enjoy the summer holidays, well-deserved after the hard work in Spring.

The Donated Antibodies Working against Novel Coronavirus (DAWN-plasma) trial is now in its 4th month after enrollment of the first patient. Looking back on what must have been the most busy months in our professional careers, we can say that the hospitals have done a tremendous job in delivering good quality care for COVID-19 patients. Setting up our trial in these circumstances was a major endeavor, and we applaud your active collaboration, without which we would never have been able to succeed. Croix Rouge as well as Rode Kruis Vlaanderen have done a tremendous job in delivering high-quality convalescent plasma, and in the set-up of the trial. And of course, this trial could never have been done without the financial, logistic, and financial support by KCE.

With this first newsletter, we would like to keep you informed on the status of the trial. We aim to send out a newsletter every 2-3 months. We will keep you updated on recruitment, number of active sites, enrollment, eventual protocol updates, or changes in procedures.

Today, 35 patients have been included in the trial, from 9 of the 22 recruiting sites. We are extremely happy and proud that we are able to collaborate with such a large group of highly motivated researchers. Given the nature of this pandemic, and the local outbreaks that now appear to characterize this second peak, the extensive geographical distribution of the DAWN-plasma network in Belgium will prove to be of major importance.

The enthusiasm and motivation of the DAWN-plasma sites is fantastic. We wish you all success in recruitment, while we all hope that we can be spared of major outbreaks.

Thank you!

Geert Meyfroidt

Timothy Devos

Myriam Cleeren

Katleen Vandenberghe

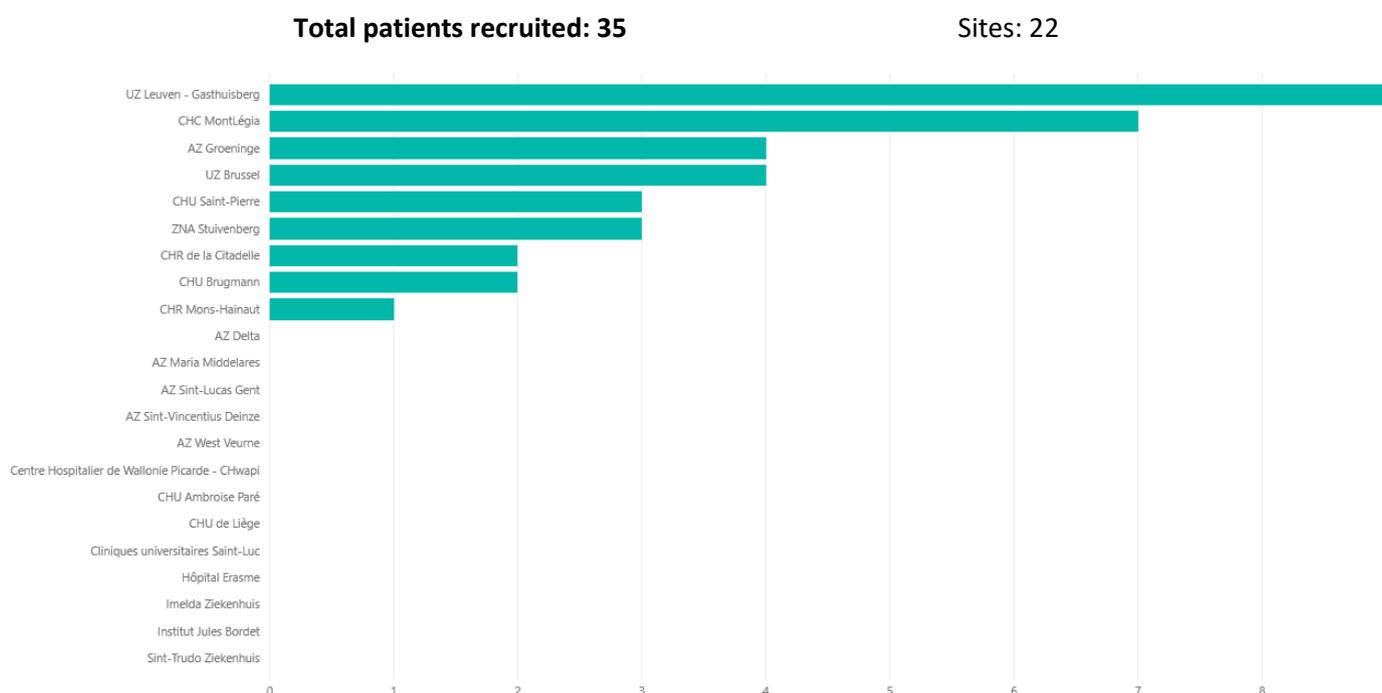
Anne Luyten



Steering Committee:
second half September 2020

KCE tool (EDGE) to follow-up recruitment

KCE is using EDGE, an online Clinical Trial Management System (CTMS), to follow-up on recruitment of all sites in the DAWN study (and of all other KCE Trials funded studies). Recruitment by site is publicly available on KCE's dynamic dashboards (<https://kce.fgov.be/en/cov201003-donated-antibodies-working-against-ncov-dawn-plasma>) which are updated every Friday. As a site participating to a KCE Trials funded study, you are entitled to have a full license to use this CTMS in your hospital to manage your own clinical studies. Currently 15 hospitals in Belgium have access to this full license. Should you be interested to hear more about EDGE, do not hesitate to contact KCE Trials for more information (trials@kce.fgov.be).



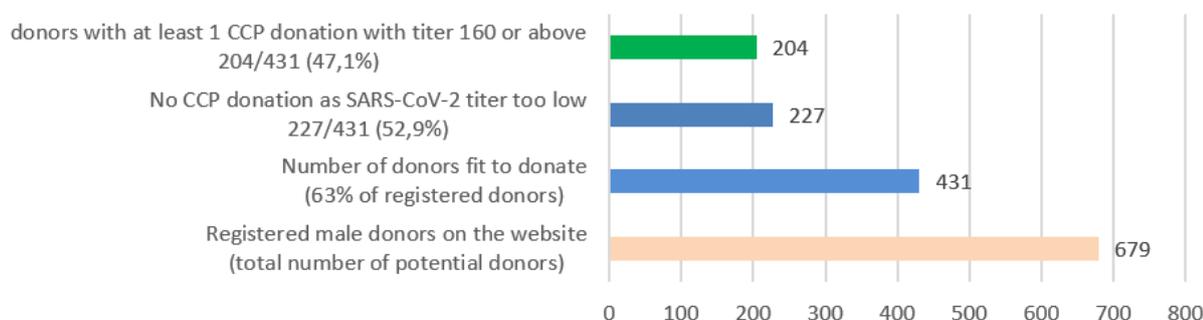
Update on availability of plasma and other news from RKV/CR

1. Rode Kruis Vlaanderen : Convalescent COVID 19 Plasma (CCP) – donor recruitment, selection and CCP donation

Red Cross Flanders started the first collections of CCP by the end of April 2020.

Up to August 2020, 679 potential donors registered at the website. All were contacted for a prescreening and if fit to donate (63%), they were invited for SARS-CoV-2 antibody testing (neutralizing antibody titers) as well as the legally required voluntary blood donor counselling and tests.

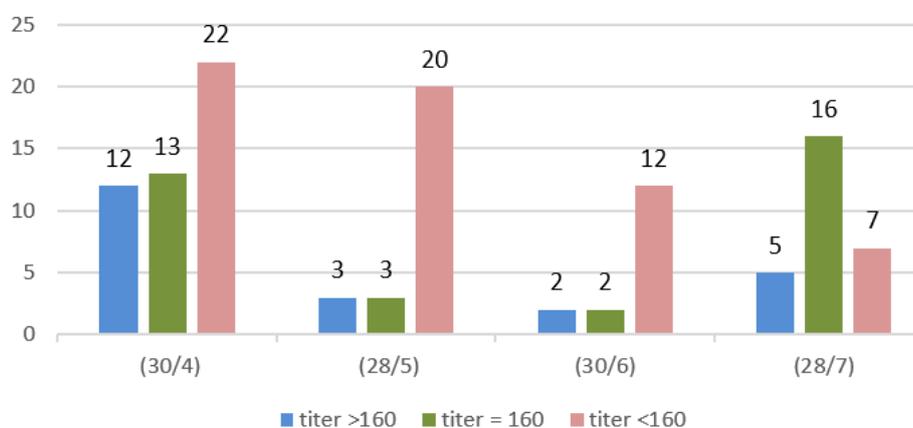
Potential CCP donors



Only half of the donors (204) that were tested (47.1 %) had an antibody titer equal or higher than 160.

The next figure shows some, 'new' donor results, received from the REGA institute. Approximately 20% have a titer higher than 160.

Number of new donor SARS-CoV-2 results received on 30/4, 28/5, 30/6 and 28/7



Finally 523 donations were realized with 204 donors. 61 donors donated once, 70 twice. On top are one donor with 10 and 2 donors with 9 donations.

SARS-CoV-2 antibody testing is repeated on donations if > 1 month evolves between testing and the last donation. We see a steady decline in antibody titer, requiring exclusion of donors to further donate CCP. Currently only around 20 % of new donors have titers >160.

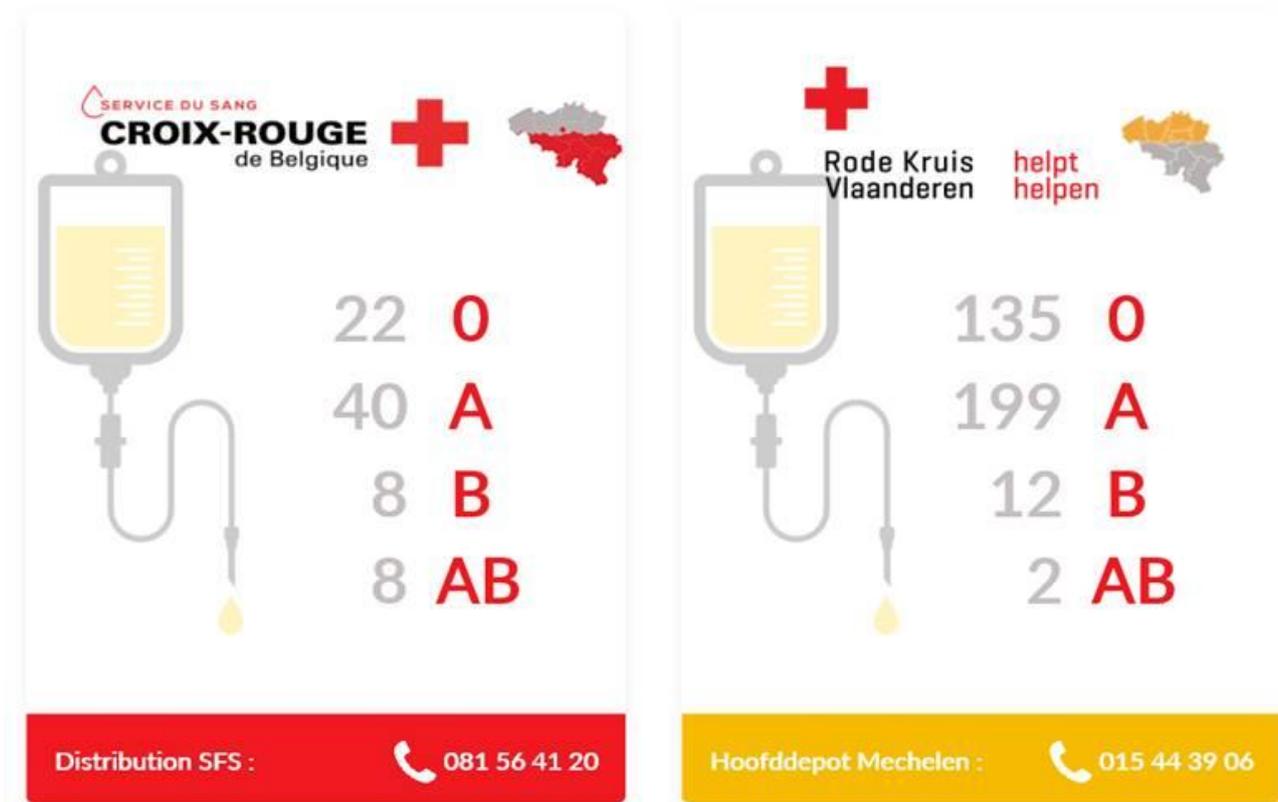
On August 2nd: 337 units CCP with titer > 160 were available as well as 282 units with titer = 160.

Most donors that tested positive in the 1st wave have currently low titers of neutralizing antibodies. It would be good to reactivate donor recruitment mid-August to select donors that were sick and tested positive in the 2nd wave of the COVID-19 outbreak.

2. Croix Rouge

There are today 234 donors. There is 78 plasmas available at a titer $\geq 1/320$ (neutralizing antibodies) and 5 waiting for validation before release authorization.

The A,B,O distribution is as follows (plasmacovid website):



FAQ

1. ICF and protocol are under review and will soon be submitted to EC
2. The list of labs for Neu AB was updated with addresses for shipping – see website
3. The ability to record the Neu AB results in the e-CRF is now available
4. Transport of the Neu AB samples to the lab is included in the per patient fee
5. Updated Q&A 2020-07-29 are on the website