CEVAC | CENTRUM VOOR VACCINOLOGIE

Setting up vaccine clinical trials in a pandemic context: experience from a study site

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UZ GENT

UNIVERSITEIT GENT

Outline

1. Introduction CEVAC
2. Recruitment
3. Operational aspects and study conduct
4. SARS-CoV-2 Surveillance
5. Availability of commercial COVID-vaccines
6. Study results

CEVAC Mission

Contribute to the development of new vaccines and the improvement of existing vaccines for the prevention of infectious diseases.

CEVAC history

- Officially founded in 1995
- > 250 vaccine trials in healthy (older) adults

CEVAC team

- Clinical trial unit with 6 investigators, 4 study coordinators, 10 study nurses
- Immunology Laboratory with 2 project managers and 10 lab technicians
- Shared QUA department with 1 QUA-manager and 2 QUA assistants

CEVAC activities during the pandemic

- New trials:
  - ✓ 6 new COVID-trials
  - ✓ 9 other new vaccine trials
- 10 ongoing trials
- Approximately 2000 healthy volunteers enrolled since March 2020

2. Recruitment

1. Recruitment for COVID-trials before the availability of a registered COVID-vaccine

2. Recruitment for other trials

1. Recruitment for COVID-trials before the availability of a registered COVID-vaccine

Coronavaccin

UZ Gent start volgende week met laatste fase van studie Johnson&Johnson-vaccin

- Huge influx of volunteers
- Desperation to be included in the trial
  - ✓ Being refused for a trial was not always well taken
  - ✓ Hold back information about medical history

Coronavaccin

UZ Gent start met grootschalige proeven van Duits coronavaccin CureVac

Meer dan 5.000 proefpersonen: "Nooit geziene opkomst voor een vaccinstudie" (UZ Gent)

21 december 2020 *door Belga en P.S.*

2. Recruitment for other trials

- Vaccine fatigue?
- Increase of vaccine hesitancy? E.g. fear for immune overload?
- Or people just want to pick up their normal lives again, travel,… ?
- Need for an awareness campaign!

FAMHP campaign (2017)

Klinischeproeven.be

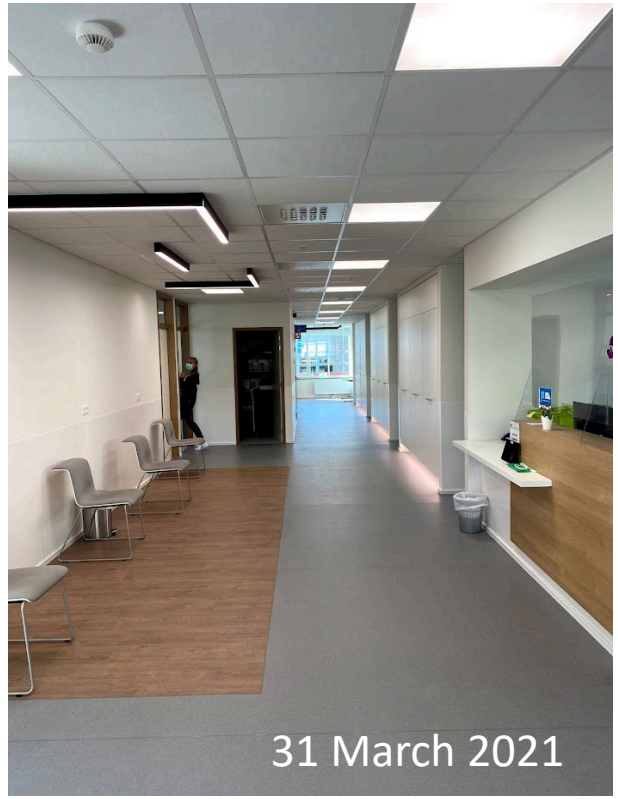
3. Operational aspects and study conduct

1. Space and personnel

- Expansion of the team

- Expansion of the unit

  From warehouse to
  clinical vaccine trial unit
  in less than 6 months



- Fast validation of new equipment

3. Operational aspects and study conduct

2. Logistics: shortage of products and reagents

3. Time pressure and exceptionally high workload

- Extremely short interval between availability of the protocol and the enrolment of the first study participant for COVID-trials
- Lab: intermediate analyses
- Short period for data-entry and resolution of queries

3. Operational aspects and study conduct

4. Protocol amendments and amendments to ICF

- Changed safety information

- Replacement of on site visites by phone calls
  (missed immunogenicity samples)

- ICF addenda in COVID trials: 3 to 7 per participant
  - ✓ Complaints
  - ✓ Create short forms in stead of revision of initial ICF

3. Operational aspects and study conduct

5. Planning: subject to many last-minute changes
   - Involvement of MD's in addendum ICF procedures
   - SARS-CoV-2-surveillance
6. Increase of non-compliance
   - Missed visits: 0,84% in 2020 → 2,7% in 2021 (eg. Confirmed COVID or suspected COVID symptoms)
   - Drop-outs: 0,83% in 2020 → 6,3% in 2021 (COVID-vaccines)
7. Phase 1 trials with sentinel subset: more back-up candidates needed

3. Operational aspects and study conduct

8. Lockdown(s): halt in enrolment and delay of study start

9. COVID safe ticket

- no possibility to register investigational vaccines
- participants declined to accept the invitation for the commercial vaccine
- Complaints/worries about travelling,…

4. SARS-CoV-2 surveillance

1. Big burden for both the clinical and the lab team, and for the participants

- Unpredictable
- Many unscheduled visits and complex procedures (all different for every trial)
- during peak periods:
  - ✓ 1 person to take phonecalls
  - ✓ 1 person to perform suspected COVID-visits

4. SARS-CoV2 surveillance

2. Certificate of recovery

- Testing was done based on subject-ID number.
  - No personnel identification
  - Test result in clinical trials sometimes took weeks
  - No official registration of infection. Additional visit to test center had to be advised.

- CTPC code: link of positive test result to personal information

5. Availability of COVID-vaccines

1. Ongoing COVID-vaccine trials

- Studies that were still enrolling: high vaccine coverage: race against the clock.
- Participants in the follow-up phase of COVID-trials:
  - ✓ Need for unblinding
  - ✓ The placebo candidates:
    - were advised to accept their invitation for the commercial vaccines.
    - depending on sponsor decision: drop-out or continue in the study after receipt of commercial vaccine.
  - ✓ IMP candidates: wait until a certain timepoint in the study (efficacy results)

Bijna 400 van 620 stapten uit vaccinstudie om gevaccineerd te kunnen worden

Het succes van de Belgische vaccinatiecampagne zorgt voor moeilijkheden bij de lopende vaccinstudies. In het Gentse Centrum voor Vaccinologie (CEVAC) zijn bijna 400 van de 620 deelnemers aan een studie naar het Duitse CureVac al uit het onderzoek gestapt omdat ze in aanmerking komen voor een door het Europees Geneesmiddelenagentschap goedgekeurd vaccin.

09/06/21 om 05:20
Bijgewerkt om 05:19
Bron : Belga

5. Availability of COVID-vaccines

2. New COVID-vaccine trials

- Unethical study concepts: Performing a placebo-controlled randomized clinical trial once the national vaccination campaign started
- Unrealistic eligibility criteria:
  Requests to start studies with subjects that:
  - ✓ Not having received COVID vaccines yet
  - ✓ No confirmed COVID-infection

6. Study results

- Impact on RSV/influenza clinical trials

- Low circulation of RSV and influenza

  → difficult to reach primary endpoint in phase 3 efficacy studies

7. Conclusions

1. Exceptional efforts were done to continue vaccine research and assist in the development of COVID vaccines.

2. Efforts are needed to convince the public of the need to contribute to vaccine research. Recruitment of study participants has never been more difficult.

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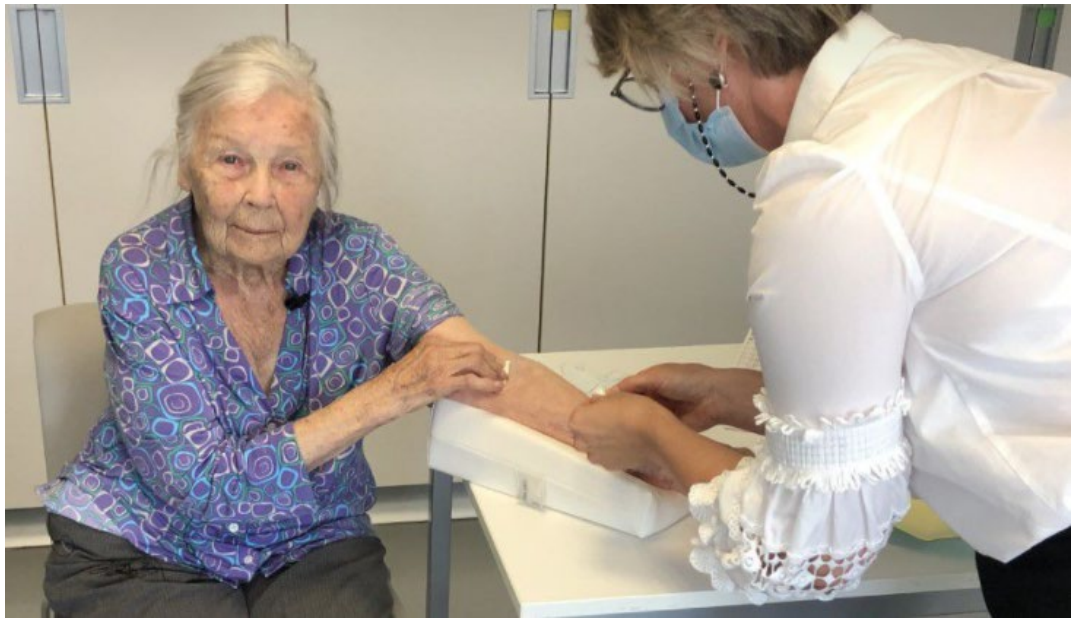
No new vaccines without …. study participants

vrt NWS



Yvonne (97) oudste proefpersoon ooit voor nieuw vaccin in UZ Gent

Deze ochtend namen de 97-jarige Yvonne De Coninck en haar 84-jarige echtgenoot uit Schelderode deel aan een studie rond een nieuw RSV-vaccin. Hiermee is ze de oudste proefpersoon ooit die deelneemt aan een klinische studie in het Gentse UZ en mogelijks in heel Vlaanderen. "Het is mijn plicht om mee te doen", zegt ze.

Rolmodel

De studie waaraan Yvonne en Renaat deelnemen duurt drie jaar. Met hun deelname hoopt het UZ dat ze een rolmodel en voorbeeld kunnen zijn voor andere 60-plussers. "Want heel wat van die mensen denken dat ze te oud zijn of hun gezondheid niet goed genoeg is, maar dat is geen enkel probleem om deel te nemen aan een klinische studie", besluit professor Leroux-Roels.

Het ziekenhuis zoekt nog extra deelnemers voor de studie.

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