Sundhedsudvalget 2022-23 (2. samling)
SUU Alm.del - Bilag 197
Offentligt

# Danmarks unikke mulighed for at være førende inden for vaccine forskning

DANFLU
Randomized
RWE

REGION Herlev og Gentofte Hospital

UNIVERSITY OF COPENHAGEN

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# RECOVERY

Randomised Evaluation of COVID-19 Therapy



This international clinical trial is identifying treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19

## GLOBAL CUMULATIVE TOTALS

**48508** Participants

**192** Active sites


A range of promising but unproven treatments have been suggested for the treatment of COVID-19 and influenza.

The RECOVERY Trial has found four treatments that are effective for severe COVID-19 and is currently testing the following suggested treatments to find out whether they are more effective in helping people recover than the standard care that all patients receive:

For COVID-19

- sotrovimab (a monoclonal antibody treatment against the spike protein)
- molnupiravir (an antiviral treatment)
- paxlovid (an antiviral treatment)

# Two years on: the COVID-19 treatment that saved millions


16 June 2022

Two years ago today, the discovery of the first-ever lifesaving treatment for COVID-19, called dexamethasone, was announced to the world.

In the following nine months, dexamethasone, an inexpensive, readily available steroid, saved an estimated one million lives worldwide, including 22,000 in the UK.

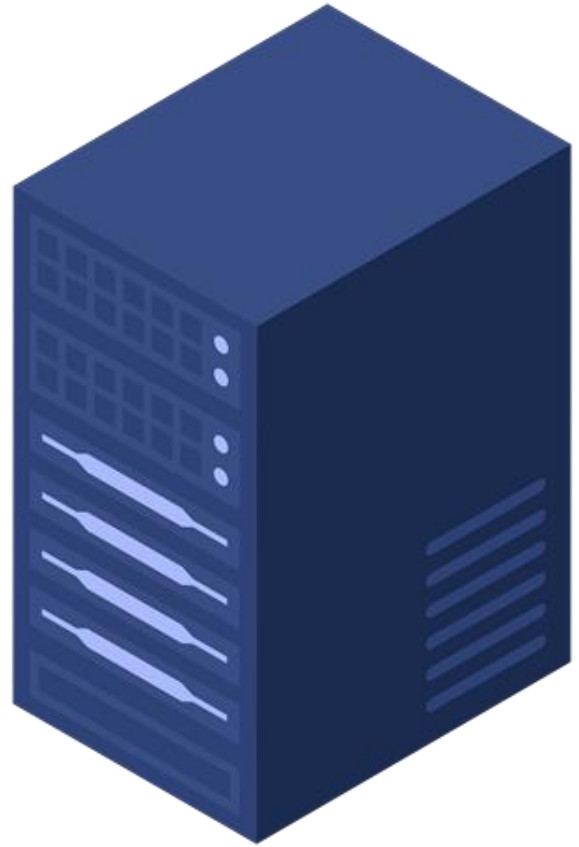
The treatment was found by researchers from the **Randomised Evaluation of COVID-19 Therapy (RECOVERY trial)**, one of the world's fastest-recruiting treatment trials in medical history.

It was primarily funded by UK Research and Innovation (UKRI) and the National Institute for Health and Care Research (NIHR) with **a joint investment of £2.1 million**. This was organised after a **call for research proposals** in early February 2020.

**Related content**

⇨ **The inside story of Recovery: how the world's largest COVID-19 trial transformed treatment – and what it could do for other diseases**


e-boks.dk



NEJM Evidence

DANFLU-1 Randomized RWE

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ORIGINAL ARTICLE

# A Pragmatic Randomized Feasibility Trial of Influenza Vaccines

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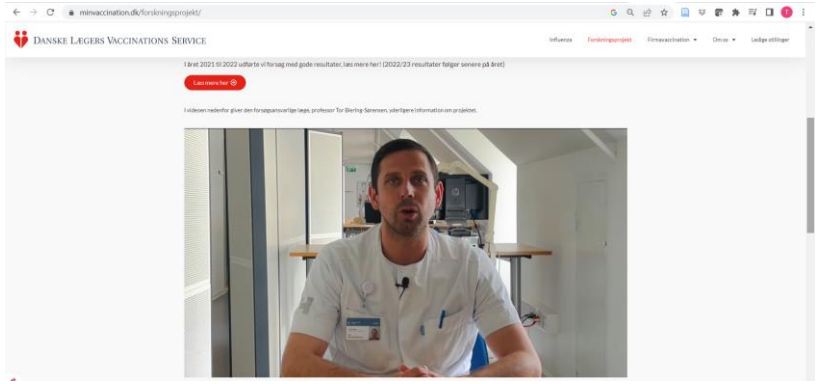
# Formål

- At evaluere gennemførligheden af integrere et individuelt randomiseret forsøg i det rutinemæssige nationale influenzavaccinationsprogram og bruge administrative sundhedsregistre til dataindsamling
- Sekundært at undersøge om en højdosis influenzavaccine (QIV-HD) reducerer indlæggelser og død i forhold til en standarddosis influenzavaccine (QIV-SD)
- I Danmark bruges standarddosis influenzavaccinen (QIV-SD) i det danske vaccinationsprogram, på trods at vi ved at højdosis influenzavaccine (QIV-HD) reducerer risikoen for influenza med 24%


**Vaccination clinic network:**

- Open year-round – not just for flu vaccination
- Vaccinates >200,000 persons/year and rapidly upscaling
- Inclusion and randomization
- Administration of study drug

Initial participant data

UNIVERSITY OF COPENHAGEN

REGION H Gentofte Hospital

**Center for Pragmatic Randomized Trials**

- Central trial site
- Study oversight
- Database management
- Nationwide access to all medical records and lab results

Participant SSN

Baseline characteristics and outcomes

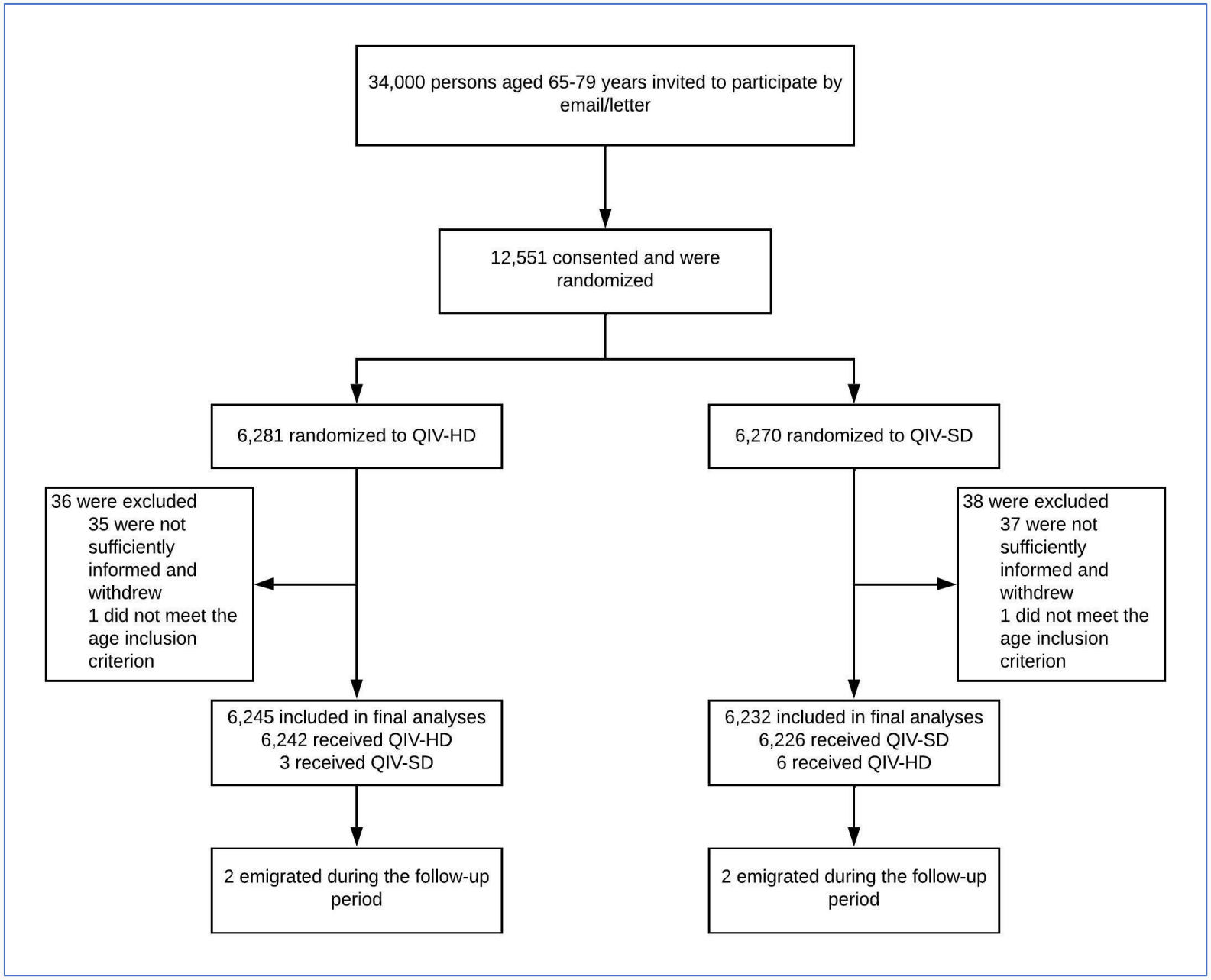
**Registry data:**

- Nationwide tax-funded public health system
- Nationwide registries can be crosslinked using social security numbers (SSN)
- Every hospital contact, death, redeemed prescription is captured in the registries

# Study flow

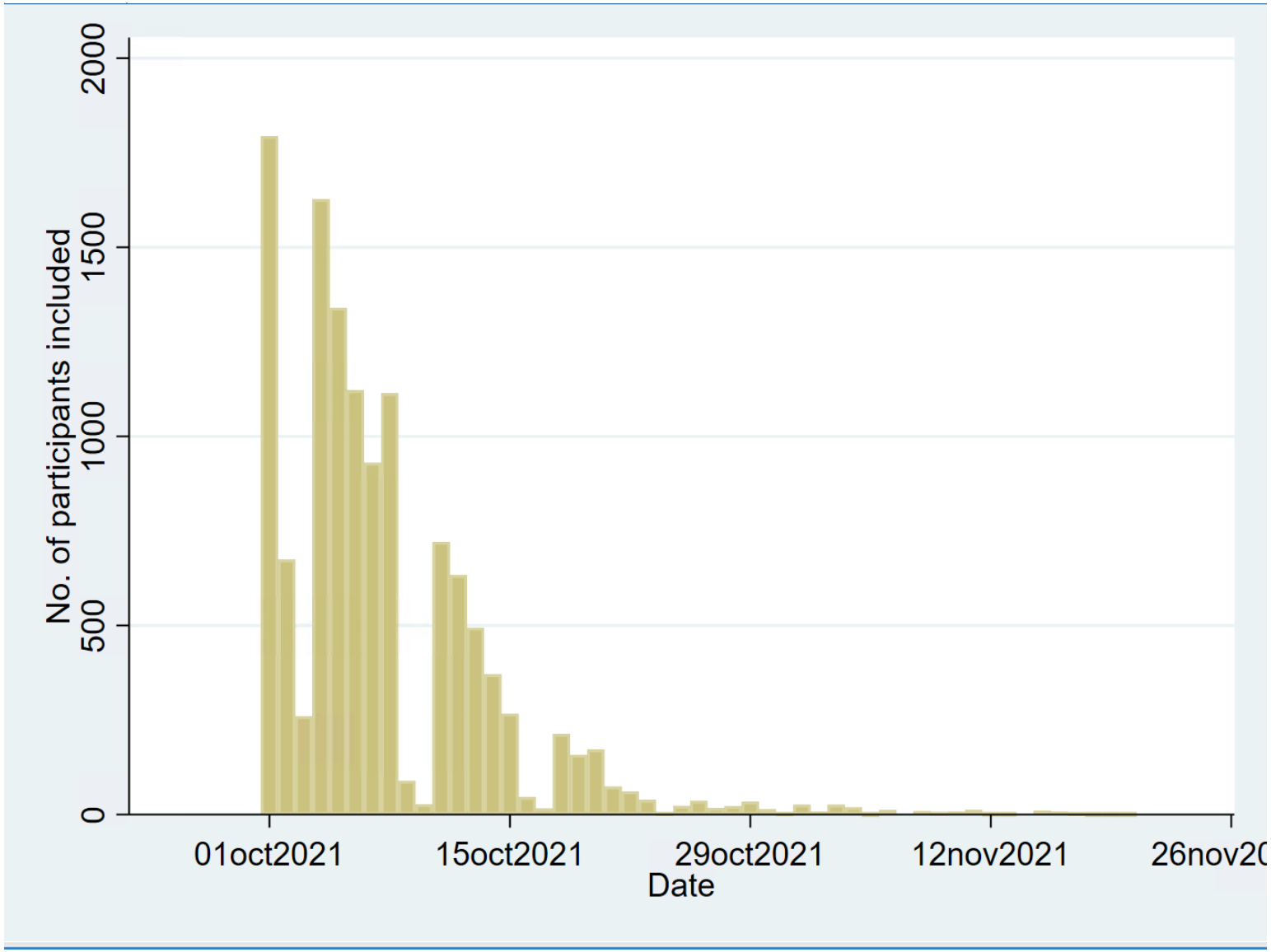
99.93% received correct study vaccine

Complete follow-up data available for 99.97% of participants



# DANFLU-1

## 12.551 recruited in approx. 4 weeks



# Baseline characteristics

| Characteristic | QIV-HD n = 6,245 | QIV-SD n = 6,232 |
|---|---|---|
| **Age, mean (SD)** | 71.8 (3.9) | 71.7 (3.9) |
| **Female sex, n (%)** | 2,956 (47.3) | 2,921 (46.9) |
| **Chronic cardiovascular disease, n (%)** | 1,227 (19.6) | 1,313 (21.1) |
| **Ischemic heart disease, n (%)** | 450 (7.2) | 512 (8.2) |
| **Heart failure, n (%)** | 137 (2.2) | 138 (2.2) |
| **Atrial fibrillation, n (%)** | 458 (7.3) | 420 (6.7) |
| **Cerebrovascular disease, n (%)** | 219 (3.5) | 237 (3.8) |
| **Hypertension, n (%)** | 3,254 (52.1) | 3,215 (51.6) |
| **Diabetes, n (%)** | 574 (9.2) | 588 (9.4) |
| **Chronic lung disease, n (%)** | 435 (7.0) | 415 (6.7) |
| **Chronic obstructive pulmonary disease, n (%)** | 227 (3.6) | 190 (3.0) |
| **Cancer, n (%)** | 695 (11.1) | 668 (10.7) |
| **Immunodeficiency, n (%)** | 244 (3.9) | 239 (3.8) |

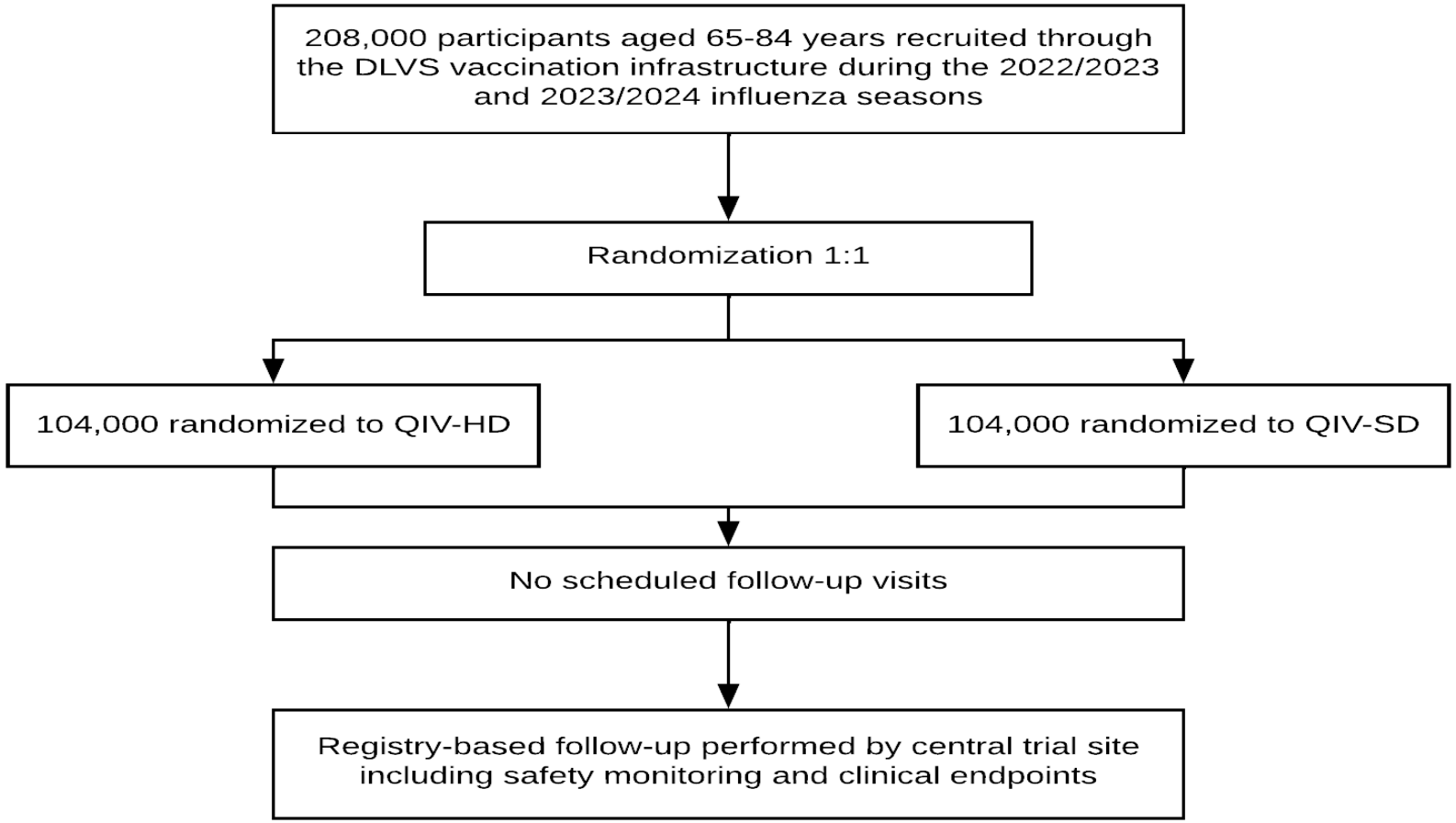
| | QIV-HD<br>n = 6,245 | QIV-SD<br>n = 6,232 | rVE (95% CI) |
|---|---|---|---|
| **Outcome** | No. of events (%) | | % |
| **Hospitalization for influenza or pneumonia** | 10 (0.2) | 28 (0.4) | 64.4 (24.4 to 84.6) |
| **Hospitalization for respiratory disease** | 24 (0.4) | 40 (0.6) | 40.1 (-1.8 to 65.5) |
| **Hospitalization for cardio-respiratory disease** | 103 (1.6) | 117 (1.9) | 12.1 (-15.5 to 33.3) |
| **Hospitalization for cardiovascular disease** | 82 (1.3) | 81 (1.3) | -1.0 (-39.1 to 26.6) |
| **Hospitalization for COVID-19** | 15 (0.2) | 12 (0.2) | -24.7 (-191.9 to 45.5) |
| **Hospitalization for any cause** | 513 (8.2) | 550 (8.8) | 6.9 (-5.2 to 17.6) |
| **All-cause death** | 21 (0.3) | 41 (0.7) | 48.9 (11.5 to 71.3) |

# DANFLU-2

Randomized RWE

Invite ~ 1.000.000 Danes in the aged and above

eBoks



# DANFLU-2 hvad er fordelene?

**For sundhedsmyndighederne vil der være flere fordele**

- **Alle de relevante godkendelser er allerede på plads**
- **Gratis vacciner stilles til rådighed**
- **Undgå unødvendige indlæggelser og dødsfald, og dermed mindske belastningen for sundhedsvæsenet**
- Studiet vil give data til det danske sundhedsvæsen, som vil hjælpe med at give det bedste grundlag for at undersøge, om højdosis vaccine er omkostningseffektiv i Danmark
- Levere verdensførende data gennem innovative forskning, der kan sætte Danmark og de danske sundhedsmyndigheder på verdenskortet, da det er muligt hurtigt at få valide data om vaccineeffektivitet. Dette vil være relevant ved fremtidige pandemier


# DANFLU-2 opsummering

**Hvorfor er vores studie godt at få inkluderet i det nationale vaccineprogram?**

- Gøre Danmark til foregangsland indenfor vaccineområdet
- Støtte op om verdens største randomiserede studie
- Være en del af forskningen inden for vaccineområdet
- Vise at sundhedsmyndighederne støtter op om forskningsmiljøet i Danmark
- Give 100.000 danskere mulighed for at få en højdosis vaccine gratis, hvilket kan forhindre dødsfald og indlæggelser grundet influenza
- Mindske belastningen på de danske hospitaler

Men dette kræver bred opbakning fra sundhedsmyndigheder og sundhedspolitikere

# Tak for opmærksomheden

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