

Vaccine	Comirnaty (BioNTech) BNT162b2
Technology	mRNA +LNP
Clinical Trial No.	NCT04368728
Ratio and blinding	1:1 randomized; observer blinded
Dose; Schedule; age	30µg, i.m., 2 doses, 21 days, >=16 yrs
Placebo/control vaccine	Placebo (saline)
study period	27.07. - 09.10.2020
No. randomized	43,548
study location	152 centres; USA, Brazil, Argentina, South Africa, Germany, Turkey
Primary efficacy outcome	COVID-19 (lab-confirmed) 7 days after dose 2
Secondary and exploratory efficacy outcomes	severe COVID-19, COVID-19-related death
Safety outcomes	Local reactions, systemic reactions, serious adverse events
Age of participants (mean, range)	Verum: 52,0 (16–89) Placebo: 52,0 (16–91)
Study population 16-55/18-64 years	Verum: 10.889 (57,7%) Placebo: 10.896 (57,8%)
Study population >55/>65 years	Verum: 7.971 (42,3%) Placebo: 7.950 (42,2%)
Study population 18-64 years with/without co-morbidities	
Sex m/f/d	Verum: 9.639 (51,1%)/9.221 (48,9%) Placebo: 9.436 (50,1%)/9.410 (49,9%)
Participants with co-morbidities	Verum: 3.934 (20,9%)/3.809 (20,2%)
Observation periods after dose 2 (median)	2 months

data cut	10/9/2020
Date of EMA approval	12/21/2020
Inclusion criteria (main)	healthy or with stable pre-existing condition
Exclusion criteria (main)	Previous COVID-19; immunological condition; women: pregnant or breast-feeding

COVID-19-Vaccine Moderna (mRNA-1273)	COVID-19 Vaccine AstraZeneca (AZD1222)	Johnson & Johnson (Ad26COVS1)
mRNA +LNP	Vector-based, not replicating	Vector-base, not replicating
NCT04470427	NCT04324606, NCT04400838, NCT04536051, NCT04444674	
1:1 randomized; observer blinded	1:1 randomized; observer blinded	
100µg, i.m., 2 doses, 28 days, >=18 yrs	µg, i.m., 2 doses, 4-12 weeks, >=18 yrs Low dose (LD; 2.2×10^{10} viral particles) or standard dose (SD; $3.5-6.5 \times 10^{10}$ viral particles)	µg, i.m., 1 Dose
Placebo (saline)	MenACWY/Placebo (saline)	Placebo
27.07 – 23.10.2020	from 23.04.2020 onwards	
30,420	32,753	
99 centres, USA	UK, Brazil, South Africa	
COVID-19 (lab-confirmed) 14 days after dose 2	COVID-19 (lab-confirmed)	
severe COVID-19, COVID-19-related death	severe COVID-19, COVID-19-related death, COVID-19-related hospitalization, asymptomatic infection	
Local reactions, systemic reactions, serious adverse events	Local reactions, systemic reactions, serious adverse events	
Verum: 51,4 (18–95)	Verum: 40,0 (18–86)	
Placebo: 51,3 (18–95)	Placebo: 40,0 (18–88)	
Verum: 11.418 (75,2%)	Verum: 5.466 (94,1%)	
Placebo: 11.421 (75,3%)	Placebo: 5.510 (94,5%)	
Verum: 3.763 (24,8%)*	Verum: 341 (5,9%)	
Placebo: 3.749 (24,7%)*	Placebo: 319 (5,5%)	
Verum: 8.888 (58,5%)		
Placebo: 8.886 (58,6%)		
Verum: 2.530 (16,7%)		
Placebo: 2.535 (16,7%)		
Verum: 7.923 (52,2%)/7.258 (47,8%)	Verum: 2.282 (39,3%)/3.525 (60,7%)	
Placebo: 8.062 (53,1%)/7.108 (46,9%)	Placebo: 2.307 (39,6%)/3.521 (60,4%)/ 1/8<0,1%)	
see above		
64 days	62 days	

11/26/2020	04.11.2020 ^a (n=11.636)/ 07.12.2020 (n=17.177) ^b	
1/6/2021		1/29/2021
healthy or with stable pre-existing condition	healthy or with stable pre-existing condition	
Previous COVID-19; immunological condition; women: pregnant or breast-feeding	Previous COVID-19; known anaphylaxis; immunodeficiency; severe pre-existing health condition; women: pregnant or breast-feeding	