

Algemene gegevens / General Information

Programma / Programme : **COVID-19 Programma**
 Subsidieronde / Subsidy round : **Bottom-up ronde COVID-19 aandachtsgebied 1**
 Projecttitel / Project title : **Therapeutic inhibition of excessive lung inflammation induced by anti-SARS-CoV-2 antibodies**
 Projecttaal / Project language : **Engels / English**
 Geplande startdatum / Planned start date : **01-08-2020**
 Geplande duur / Planned duration : **12 maanden / months**
 Datum indienen / Date of application : **16-06-2020**
 Projecttype / Project type : **Fundamenteel onderzoek**
 Vervolg eerder ZonMw-project / Continuation previously funded project : **Nee / No**
 ZonMw

Projectleden / Project members

5.1.2e
 Functie / Position: 5.1.2e | Opleiding / Education:
 Studierichting / Subject:
 T: 5.1.2e F: | E: 5.1.2e @amsterdamumc.nl

Amsterdam UMC - locatie AMC
 Klinische Immunologie & Reumatologie
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 Studierichting / Subject:
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Amsterdam UMC, locatie VUmc
 Longziekten
 Postbus 19268
 1000 GG AMSTERDAM

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 Studierichting / Subject:
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Medische Biochemie
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5.1.2e
 Functie / Position: 5.1.2e | Opleiding / Education:
 Studierichting / Subject:
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Sanquin Research
 Experimentele Immunohematologie
 Postbus 9892
 1006 AN AMSTERDAM

Projectgegevens / Project information

Aandachtsgebieden / Focus

- 1.1 Thema's aandachtsgebied 1
- Virus, immuniteit, immuunrespons en pathogenese

Samenvatting / Summary

RESEARCH QUESTION

5.1.2i Wetenschappelijk beraad

URGENCE

5.1.2i Wetenschappelijk beraad

HYPOTHESIS

5.1.2i Wetenschappelijk beraad

APPROACH

5.1.2i Wetenschappelijk beraad

Trefwoorden / Keywords

Antibodies, Inflammation, Macrophages, Airway epithelium, Fc receptor, Cytokines, COVID-19, SARS-CoV-2

Samenwerking / Collaboration**Samenwerking tussen onderzoek en praktijk / Cooperation between research and practice:**

Nee / No

Organisaties

Leids Universitair Medisch Centrum
 Parasitologie
 Postbus 9600
 2300 RC LEIDEN

Sanquin Bloedbank
 Onderzoek en Ontwikkeling

Financiële gegevens / Financial data**ZonMw budget**

	Jaar / Year								
Kostenpost	1	2	3	4	5	6	7	8	Totaal / Total
Personeel	5.1.1c								
Materieel									
Implementatie									
Apparatuur									
Overig									
Totaal / Total									

Co-financiering / Cofinancing

Naam co-financier / Name of cofinancier	Bedrag / Amount	Status
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Bijzondere gegevens / Additional information**Vergunningen / Permits**

	Verklaring nodig / Statement required?		Status verklaring / Statement status		
	Ja / Yes	Nee / No	Verkregen / Acquired	Aangevraagd / Applied	Nog niet aangevraagd / Not applied yet
METC		X	X		
DEC		X			
WBO		X			

Onderschrijvingen / Assents

	Ja / Yes	Nee / No	N.v.t. / N.A.
Code biosecurity / Code Biosecurity			X
Code openheid dierproeven / Code Transparency of Animal Testing			X

Andere vergunningen / Other permits

AANVRAAGFORMULIER

UITGEWERKTE SUBSIDIEAANVRAAG

– BOTTOM-UP RONDE

COVID 19 programma

Deadline voor indiening: 15 juni 2020 (14:00 u)

**LEES ALSTUBLIEFT ALLE INSTRUCTIES IN BIJLAGE "TOELICHTING
INDIENING SUBSIDIEAANVRAAG" VAN DE OPROEPTEKST ZORGVULDIG!**

Wanneer u het formulier heeft ingevuld:

1. Zet het formulier om naar een PDF file en controleer de details
 2. Upload het complete formulier als een bijlage bij uw indiening in Projectnet
(Let op: dit zijn twee verschillende links, gebruik maar 1 van de 2!)
- ProjectNet: [Aandachtsgebied 1 \(voorspellende diagnostiek en behandeling\)](#)
ProjectNet: [Aandachtsgebied 2 \(zorg en preventie\)](#)

BASISGEGEVENS (voorpagina)

NAAM VAN DE HOOFDAANVRAGER:

5.1.2e

In collaboration with:

5.1.2e

ORGANISATIE:

Amsterdam UMC, location AMC

In collaboration with:

Amsterdam UMC, location VUmc
Sanquin
LUMC

ENGELSE PROJECTTITEL:

Therapeutic inhibition of excessive lung inflammation induced by anti-SARS-CoV-2 antibodies

NEDERLANDSE PROJECTTITEL:

Het remmen van de extreme ontstekingsreactie door verkeerde soort antistoffen tegen het coronavirus in ernstig zieke COVID-19 patiënten

ONDERZOEKSVOORSTEL max 8 pagina's A4 (inclusief literatuurreferenties)	(voorpagina met basisgegevens niet meegerekend - font type Arial 10 pts)
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1. PROBLEEMSTELLING, URGENTIE EN DOELSTELLING(EN)

Patients suffering from COVID-19 are at particular risk for acute respiratory distress syndrome (ARDS) and death by respiratory failure¹. Severe cases of COVID-19 show excessive inflammation induced by a cytokine storm characterized by key pro-inflammatory cytokines such as IL-6^{2,3}, while anti-viral cytokines such as type I IFN are suppressed by the virus^{4,5}. In addition, severe patients suffer from oedema and thrombosis⁶. To date, no explanation has been put forward why many patients become critically ill around 1.5 weeks after onset of symptoms. Interestingly, this is exactly at the time of activation of adaptive immunity and rise of anti-CoV-2 antibodies⁷. Previously, it has been shown that the virus leading to SARS, SARS-CoV, causes severe inflammation and lung injury through IgG antibodies⁸. Using a SARS-CoV macaque model, Liu et al. demonstrated that the early emergence of anti-CoV Spike-protein IgGs induces severe lung injury by skewing macrophage polarization in the lungs away from wound-healing "M2" characteristics towards a strong pro-inflammatory phenotype. Notably, SARS patients that eventually died from infection displayed similar conversion of these wound-healing macrophages, as well as the early and high presence of neutralizing IgG antibodies. The pro-inflammatory consequences of these IgGs could be suppressed by blocking Fc receptor (FcR) signaling. Very similar to SARS, severe COVID-19 patients are characterized by an early rise and high titers of IgG antibodies^{9,10,11} and show a similar conversion from anti- to pro-inflammatory lung macrophages¹².

5.1.2i Wetenschappelijk beraad

5.1.2i Wetenschappelijk beraad

5.1.2e

5.1.2e

5.1.2e

5.1.2e

5.1.2b

3. PLAN VAN AANPAK (ONDERBOUW KEUZES)

DESIGN	
Key Objective 1:	5.1.2i Wetenschappelijk beraad
Part A:	5.1.2i Wetenschappelijk beraad
5.1.2e	
5.1.2i Wetenschappelijk beraad	
Part B:	5.1.2i Wetenschappelijk beraad
5.1.2i Wetenschappelijk beraad	

5.1.2i Wetenschappelijk beraad	
Key Objective 2:	5.1.2i Wetenschappelijk beraad
5.1.2i Wetenschappelijk beraad	
5.1.2i Wetenschappelijk beraad	
STUDY POPULATION	
5.1.2i Wetenschappelijk beraad	
EXPECTED OUTCOME	
5.1.2e	5.1.2e
DATA-ANALYSIS	
5.1.2e	5.1.2i Wetenschappelijk beraad 5.1.2e
POWER CALCULATION	
5.1.2i Wetenschappelijk beraad	

5.1.2i Wetenschappelijk beraad

4. PLAN VAN AANPAK (ONDERBOUW KEUZES)

TIME LINE

5.1.2i Wetenschappelijk beraad

FEASIBILITY

5.1.2i Wetenschappelijk beraad

5. RELEVANTIE

SPECIFIC FOR THIS CALL

5.1.2i Wetenschappelijk beraad

ZONMW IN GENERAL

5.1.2i Wetenschappelijk beraad

5.1.2i Wetenschappelijk beraad

6. PROJECTGROEPLEDEN EN HUN ROLLEN

For this proposal we have set up a collaboration with experts in various relevant disciplines:

5.1.2e

7. KENNISOVERDRACHT, IMPLEMENTATIE, BESTENDIGING

5.1.2i Wetenschappelijk beraad

5.1.2e

8. DEELNAME VAN DE STAKEHOLDER(S)/EINDDOELGROEPEN

5.1.2i Wetenschappelijk beraad

9. LITERATUURREFERENTIES:

1. Chen, Y. & Li, L. SARS-CoV-2: virus dynamics and host response. *The Lancet Infectious Diseases* 20, 515-516 (2020).
2. Del Valle, D.M. et al. An inflammatory cytokine signature helps predict COVID-19 severity and death. *medRxiv* (2020).
3. Herold, T. et al. Level of IL-6 predicts respiratory failure in hospitalized symptomatic COVID-19 patients. *medRxiv* (2020).
4. Hadjadj, J. et al. Impaired type I interferon activity and exacerbated inflammatory responses in severe Covid-19 patients. *medRxiv* (2020).
5. Park, A. & Iwasaki, A. Type I and Type III Interferons - Induction, Signaling, Evasion, and Application to Combat COVID-19. *Cell Host Microbe* (2020).
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7. Tay, M.Z., Poh, C.M., Renia, L., MacAry, P.A. & Ng, L.F.P. The trinity of COVID-19: immunity, inflammation and intervention. *Nat Rev Immunol* 20, 363-374 (2020).
8. Liu, L. et al. Anti-spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection. *JCI Insight* 4 (2019).
9. Huang, A.T. et al. A systematic review of antibody mediated immunity to coronaviruses: antibody kinetics, correlates of protection, and association of antibody responses with severity of disease. *medRxiv* (2020).
10. Long, Q.X. et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. *Nat Med* (2020).
11. To, K.K.-W. et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. *The Lancet Infectious Diseases* 20, 565-574 (2020).
12. Liao, M. et al. Single-cell landscape of bronchoalveolar immune cells in patients with COVID-19. *Nat Med* (2020).
13. den Dunnen, J. et al. IgG opsonization of bacteria promotes Th17 responses via synergy between TLRs and FcγRIIIa in human dendritic cells. *Blood* 120, 112-121 (2012).
14. Golebski, K. et al. FcγRIII stimulation breaks the tolerance of human nasal epithelial cells to bacteria through cross-talk with TLR4. *Mucosal Immunol* 12, 425-433 (2019).
15. Hansen, I.S. et al. FcαRI co-stimulation converts human intestinal CD103(+) dendritic cells into pro-inflammatory cells through glycolytic reprogramming. *Nat Commun* 9, 863 (2018).
16. Hoepel, W., Golebski, K., van Drunen, C.M. & Dunnen, J.d. Active control of mucosal tolerance and inflammation by human IgA and IgG antibodies. *Journal of Allergy and Clinical Immunology* (2020).
17. Vogelpoel, L.T. et al. Fcγ receptor-TLR cross-talk elicits pro-inflammatory cytokine production by human M2 macrophages. *Nat Commun* 5, 5444 (2014).
18. Chua, R.L., Lukassen, S. & Trump, S. Cross-talk between the airway epithelium and activated immune cells defines severity in COVID-19. *medRxiv* (2020).
19. Sungnak, W. et al. SARS-CoV-2 entry factors are highly expressed in nasal epithelial cells together with innate immune genes. *Nat Med* (2020).
20. Li, L., Huang, Q., Wang, D.C., Ingbar, D.H. & Wang, X. Acute lung injury in patients with COVID-19 infection. *Clin Transl Med* 10, 20-27 (2020).
21. Becker, R.C. COVID-19 update: Covid-19-associated coagulopathy. *J Thromb Thrombolysis* (2020).
22. Botros, L. et al. Bosutinib prevents vascular leakage by reducing focal adhesion turnover and reinforcing junctional integrity. *J Cell Sci* 133 (2020).
23. Manz, X.D. et al. In Vitro Microfluidic Disease Model to Study Whole Blood-Endothelial Interactions and Blood Clot Dynamics in Real-Time. *J Vis Exp* (2020).
24. Jennewein, M.F. & Alter, G. The Immunoregulatory Roles of Antibody Glycosylation. *Trends Immunol* 38, 358-372 (2017).
25. Vidarsson, G., Dekkers, G. & Rispens, T. IgG subclasses and allotypes: from structure to effector functions. *Front Immunol* 5, 520 (2014).
26. Larsen, M.D. et al. Afucosylated immunoglobulin G responses are a hallmark of enveloped virus infections and show an exacerbated phenotype in COVID-19. *bioRxiv* (2020).
27. Ackerman, M.E. et al. Natural variation in Fc glycosylation of HIV-specific antibodies impacts antiviral activity. *J Clin Invest* 123, 2183-2192 (2013).
28. Wang, T.T. et al. IgG antibodies to dengue enhanced for FcγRIIIa binding determine disease severity. *Science* 355, 395-398 (2017).
29. Chakraborty, S. et al. Symptomatic SARS-CoV-2 infections display specific IgG Fc structures. *medRxiv* (2020).
30. Chen, H.J. et al. Meta-Analysis of in vitro-Differentiated Macrophages Identifies Transcriptomic Signatures That Classify Disease Macrophages in vivo. *Front Immunol* 10, 2887 (2019).
31. Hoepel, W. et al. FcγRIII-TLR Cross-Talk Enhances TNF Production by Human Monocyte-Derived DCs via IRF5-Dependent Gene Transcription and Glycolytic Reprogramming. *Front Immunol* 10, 739 (2019).
32. Liu, D. & Mamorska-Dyga, A. Syk inhibitors in clinical development for hematological malignancies. *J Hematol Oncol* 10, 145 (2017).
33. Brouwer, P.J.M. et al. Potent neutralizing antibodies from COVID-19 patients define multiple targets of vulnerability. *bioRxiv* (2020).
34. Everts, B. et al. TLR-driven early glycolytic reprogramming via the kinases TBK1-IKKε supports the anabolic demands of dendritic cell activation. *Nat Immunol* 15, 323-332 (2014).

Reactie op opmerkingen in e-mail met positief advies

5.1.2i Wetenschappelijk beraad

5.1.2e

5.1.2e

5.1.2e

DAEB Format				
Organisation	Type of organisation	Quoted costs	Quoted co-funding	Requested budget
Amsterdam UMC - locatie AMC	Knowledge institution	5.1.1c		
Sanquin Research	Knowledge institution			
LUMC	Knowledge institution			
	Total			

Staff costs							
Function (will be filled based on "staff" sheet)	Remarks	Organisation (dropdown menu)	Costs	Own contribution / 3rd party co-funding	Requested budget ZonMw		
PostDoc 1		Amsterdam UMC - locatie AMC	5.1.1c	-	5.1.1c		
PostDoc 2		Amsterdam UMC - locatie AMC		-			
Analist		Amsterdam UMC - locatie AMC		-			
to be specified				-			
to be specified				-			
to be specified				-			
to be specified				-			
to be specified				-			
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to be specified				-			
to be specified				-			
				€		-	€

Material, equipment & consumer goods (itemised)					
Description	Remarks	Organisation (dropdown menu)	Costs	Own contribution / 3rd party co-funding	Requested budget ZonMw
Material	5.1.2i Wetenschappelijk beraad	Amsterdam UMC - locatie AMC	5.1.1c	-	5.1.1c
		Amsterdam UMC - locatie AMC		-	
		Amsterdam UMC - locatie AMC		-	
		Amsterdam UMC - locatie AMC		-	
		Amsterdam UMC - locatie AMC		-	
Implementation and communication		Amsterdam UMC - locatie AMC	-	-	-
Equipment		Amsterdam UMC - locatie AMC	-	-	-
			€	-	€
			€	-	€
			€	-	€

[illegible]

Specification staff

1.a Staff costs (based on salary scale)

nr	Function / Name	NFU / VSNU member / other staff ruling	Function/Scale	Months	Gross salary - based on table 1.1.1 ETB	Monthly Gross salary (for Other	% fte (for the project)	Salary costs	Gross salary, 40% increment (for Other ruling only)	Overhead % (for Other ruling only)	Total
1	PostDoc 1	NFU	PostDoc	5.1.2i Wetenschappelijk beraad	5.1.1c		5.1.2i Wetenschappelijk beraad				
2	PostDoc 2	NFU	PostDoc								
3	Analist	NFU	NWCH								
4	to be specified				€ 0						
5	to be specified				€ 0		100%	€ -	€ -		€ -
6	to be specified				€ 0		100%	€ -	€ -		€ -
7	to be specified				€ 0		100%	€ -	€ -		€ -
8	to be specified				€ 0		100%	€ -	€ -		€ -
9	to be specified				€ 0		100%	€ -	€ -		€ -
10	to be specified				€ 0		100%	€ -	€ -		€ -
11	to be specified				€ 0		100%	€ -	€ -		€ -
12	to be specified				€ 0		100%	€ -	€ -		€ -
13	to be specified				€ 0		100%	€ -	€ -		€ -
14	to be specified				€ 0		100%	€ -	€ -		€ -
15	to be specified				€ 0		100%	€ -	€ -		€ -

1.b Staff costs (based on hourly rate)

The hourly rate should be acceptable, reasonable and fair

nr	Function	Activity / Actions	Hourly rate	number of hours	Total
1	to be specified		€ -		€ -
2	to be specified		€ -		€ -
3	to be specified		€ -		€ -
4	to be specified		€ -		€ -
5	to be specified		€ -		€ -
6	to be specified		€ -		€ -
7	to be specified		€ -		€ -
8	to be specified		€ -		€ -
9	to be specified		€ -		€ -
10	to be specified		€ -		€ -
11	to be specified		€ -		€ -
12	to be specified		€ -		€ -
13	to be specified		€ -		€ -
14	to be specified		€ -		€ -
15	to be specified		€ -		€ -

Onderbouwing voor het voorgestelde budget

Tijdpad

5.1.2i Wetenschappelijk beraad

Personeel

5.1.2i Wetenschappelijk beraad

Materialen

				5.1.2b
		5.1.2i Wetenscl	5.1.2e	ad
				5.1.2b
5.1.2b	5.1.2b	5.1.2b		

Overigen

5.1.2i Wetenschappelijk beraad	5.1.2b
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Checklist

for Open science & FAIR data elements in the COVID-19 research programme

Version 1.1 26 May 2020

This checklist is for the first 4 out of 8 requirements and recommendations for the activities for open science and FAIR data. They relate to the preparation phase of a research project.

The checklist shows a number of options for open science and FAIR data. Please consult [Open science in COVID-19 research](#) for more information about what you can do, for recent updates on the guidance, new practices, and instructions.

Choose the options that suit your project best!

The purpose of the checklist is to fill in the options that you choose for your project. Discuss with your data steward (or other data expert) the options that suit your project best. If you have options that are not listed below, you may indicate this as well.

Please fill in the form and attach it to your grant application.

Requirements & Recommendations	Applicants must report as follows
The preparation phase: grant application	
Who is the data steward who supports the open science and FAIR data planning in your project? Check the website for ZonMw's webinars to inform and support data stewards.	☒ I involve a data steward: Name: 5.1.2e Institute: Clinical Research Unit E-mail: 5.1.2e@amsterdamumc.nl ☐ I do not have a data steward yet, because <i>Klik of tik om tekst in te voeren.</i>
Requirement 1: Alignment and reuse Please show the options for reusing data, biological materials, and/or other resources (from research or from practice) in your project. Check whether it is possible to use resources that are made in the context of COVID-19.	Name the existing resources that you plan to use: 5.1.2i Wetenschappelijk beraad ☐ Other resources, i.e. <i>Klik of tik om tekst in te voeren.</i> ☐ No, I will not use existing resources, because <i>Klik of tik om tekst in te voeren.</i> Please mark the resources that you indicated above in bold if it is a COVID-19 related resource
Requirement 2: preregistration of all animal studies	☐ In case of preregistration: Provide the link or registration code: <i>Klik of tik om tekst in te voeren.</i>

(for all other studies, preregistration is strongly recommended) You are required (for animal studies) and recommended (for all other studies) to preregister your research plan (including the protocols, methods, etc).	☐ For animal studies, the code at the Preclinical Trial Register is: Klik of tik om tekst in te voeren. ☒ No, I do not preregister my research proposal.
Requirement 3: FAIR data within COVID-19 research community Choose the options that suit your project best! Here you can show the COVID-19 specific standards, technology or infrastructure for FAIR data that you have selected to apply during your project. Once your application is granted, you can use these to fill in your data management plan (DMP) (= requirement 5). Read for more information: Open science in COVID-19 research and 3.Creating FAIR data, tailored to COVID-19	Name the COVID-19 specific FAIR data standards, technologies or infrastructure that are applicable in your study, and you plan to use: ☐ eCRF of the WHO (machine actionable) ☒ A COVID-19 related or other FAIR data point ☒ COVID-19 research platform for data sharing ☒ Data will be recorded in RDF format ☒ I plan to use the metadata scheme that will be developed for COVID-19 research (planned in summer 2020) ☒ Other COVID-19 related standards, etc: Klik of tik om tekst in te voeren. ☒ Collaboration with COVID-19 data collection(s) Wetenschappelijk b 5.1.2i Wetenschappelijk beraad ☐ A new standard, technology or infrastructure will be developed in the project with the COVID-19 research community, namely Klik of tik om tekst in te voeren. Comment on your choice(s) The exact platforms and ways of data sharing that we will apply greatly depends on how these platforms develop and whether they are suitable for our data (mainly RNAseq). In consultation with our data steward we will choose appropriately. ☐ None of the above. Comment: Klik of tik om tekst in te voeren. ☒ I did not decide yet.
Requirement 4: Budget for FAIR data and Open Access Publications You need to plan a budget for open science and research data management during your research project. This budget should include costs for data stewardship, and – if applicable - costs for additional services from data service providers (e.g. from Health-RI or other providers), or extra e-infrastructure.	Explain how you budgeted for open science and FAIR data in your project: ☐ I specified the costs in the budget form. ☒ I cannot specify the costs right now, and make a reservation of 5% maximum of my research budget for data stewardship. ☐ I did not budget the costs, because Klik of tik om tekst in te voeren. When you fill in the budget form, you could consider the following aspects: ○ Data stewardship ○ Data services providers

	○ Additional e-infrastructure, exceeding the regular institutional infrastructure. ○ Other open science and FAIR data related costs. ○ (Optional) Open access publication(s): ZonMw requires researchers within the covid-19 programme to make all publications resulting from scientific research, that is fully or partially subsidised by ZonMw, immediately (without embargo) open access available with an open license. You are allowed to include costs for <u>full gold</u> Open Access publications in the project budget up to a maximum amount of € 5000,- (specify with 'Open Access'). Immediate Open Access publishing via other routes is also permitted, but ZonMw does not provide financial resources for this. For the specific conditions we kindly refer to the programme texts.
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