

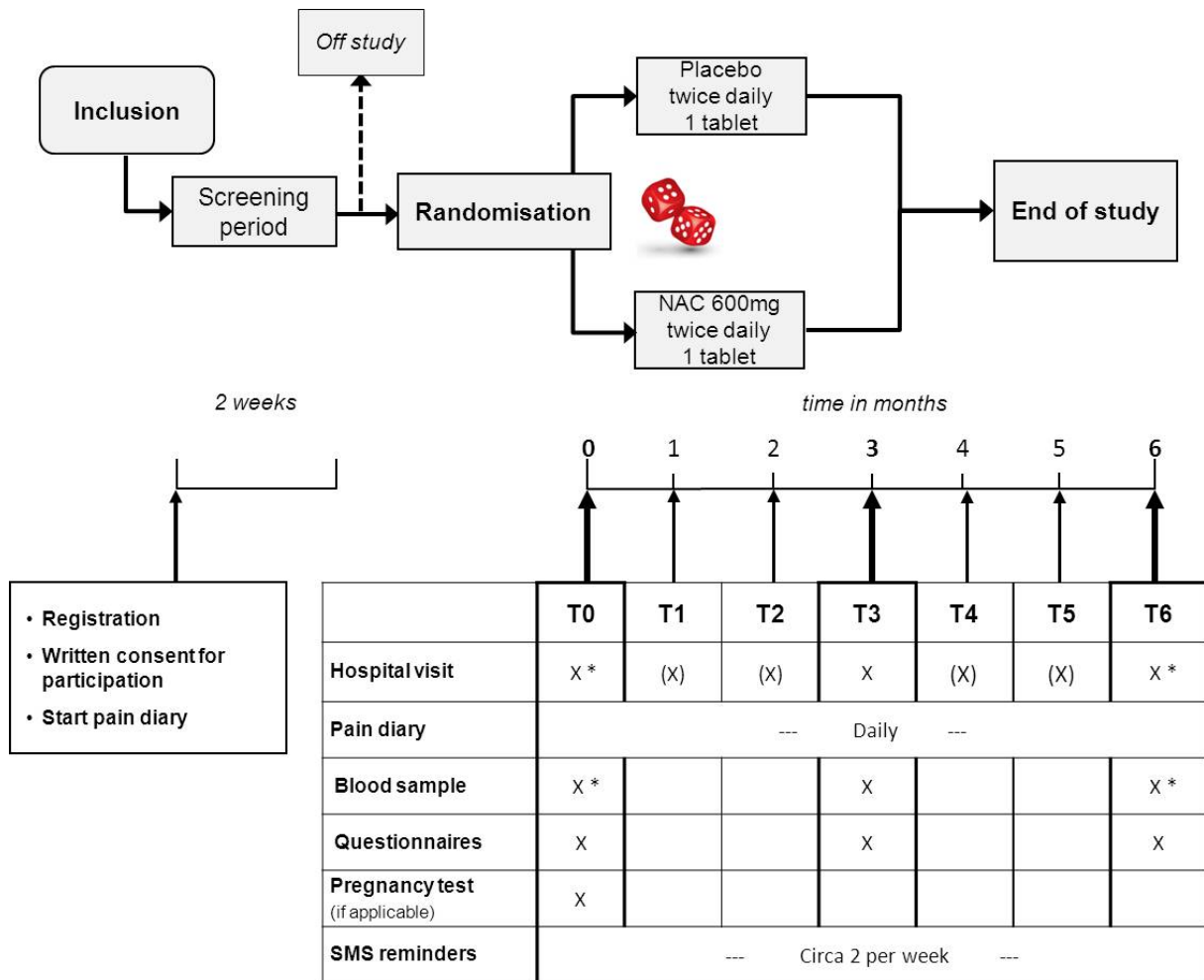
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STUDY OVERVIEW

Study flow chart



* Part of standard care

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CHECKLIST

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Study visit CHECKLIST

This checklist is designed to guide the investigator through all the required study actions at each study visit. This is not a source document and it is not meant for data collection.

CHECKLIST

REGISTRATION / SCREENING CHECKLIST																									
1. Date visit:	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> <td style="border: 1px solid black; width: 25px; text-align: center;"> </td> </tr> <tr> <td style="text-align: center;">d</td> <td style="text-align: center;">d</td> <td style="text-align: center;">m</td> <td style="text-align: center;">m</td> <td style="text-align: center;">y</td> <td style="text-align: center;">y</td> <td style="text-align: center;">y</td> <td style="text-align: center;">y</td> <td style="text-align: center;">2</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1</td> <td style="text-align: center;"> </td> </tr> </table>													d	d	m	m	y	y	y	y	2	0	1	
d	d	m	m	y	y	y	y	2	0	1															
2. Type of visit	Hospital visit																								
3. Informed consent study participation	<input type="checkbox"/> Patient <input type="checkbox"/> Parent (if applicable)																								
4. Consent text message service	<input type="radio"/> Yes <input type="radio"/> No																								
5. Registration form (form I)	<input type="checkbox"/> Completed <input type="checkbox"/> Sent / faxed																								
6. Registration number (generated by trial office)	NAC __ __ __																								
7. Pain diary for run-in period	<input type="checkbox"/> Administered																								
8. Appointment for next visit T0 (≥2 weeks)	<input type="checkbox"/> Made																								
9. Completed by: (Name researcher)																								
*** END OF REGISTRATION VISIT ***																									

VISIT T0 (RANDOMISATION) CHECKLIST	
1. Date visit:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> d d m m y y y y
2. Type of visit	Hospital visit
3. Randomisation form (form II)	<input type="checkbox"/> Completed <input type="checkbox"/> Sent / faxed
4. Randomisation number (generated by trial office)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
5. Study data sheet physician	<input type="checkbox"/> Questions T0 completed
6. Questionnaire T0	<input type="checkbox"/> Completed by patient
7. Bloodsample T0 (see manual)	<input type="checkbox"/> Drawn <input type="checkbox"/> Standard lab
	<input type="checkbox"/> Centrifuge / plasma storage
8. Study medication (give number)	<input type="checkbox"/> Administered: <input type="text"/> containers
9. Pain diary (give number)	<input type="checkbox"/> Administered: <input type="text"/> diaries
10. Text message reminders (e-mail j.w.sins@amc.nl with tel. number and start date)	<input type="radio"/> Activated <input type="radio"/> Not applicable
11. Appointment for next visit T1 (ca. 4 weeks)	<input type="checkbox"/> Made
12. Travel cost voucher	<input type="checkbox"/> Given
13. Completed by: (Name researcher)
*** END OF T0 VISIT ***	

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VISIT AFTER 1 MONTH - T1

CHECKLIST

Randomisation number:

VISIT T1 (1 month) CHECKLIST

1. Date visit T1:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> d d m m y y y y	
2. Type of visit	<input type="radio"/> <i>By phone</i> <input type="radio"/> <i>Hospital visit</i>	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked <i>- Check the diary days, discuss any unclarities or uncompleted days</i> <i>- <u>Collect</u> and <u>save</u> diary in study file</i>	
4. Pain diary in/out (give numbers)	<input type="checkbox"/> Returned <input type="text"/> diaries	<input type="checkbox"/> Administered new <input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked <i>- Discuss compliance</i> <i>- <u>Collect</u> and <u>save</u> used medication container with remaining tablets</i> <i>- Do <u>not</u> open container</i>	
6. Study medication in/out (give numbers)	<input type="checkbox"/> Returned: <input type="text"/> containers	<input type="checkbox"/> Administered new: <input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T1 completed	
8. Appointment for next visit	<input type="checkbox"/> Made	
9. Travel cost voucher	<input type="checkbox"/> Given	
10. Completed by: (Name researcher)	

*** END OF T1 VISIT ***

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VISIT AFTER 2 MONTHS - T2

CHECKLIST

Randomisation number:

VISIT T2 (2 months) CHECKLIST		
1. Date visit T2:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> d d m m y y y y	
2. Type of visit	<input type="radio"/> <i>By phone</i> <input type="radio"/> <i>Hospital visit</i>	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked <i>- Check the diary days, discuss any unclarities or uncompleted days - <u>Collect</u> and <u>save</u> diary in study file</i>	
4. Pain diary in/out (give numbers)	<input type="checkbox"/> Returned <input type="text"/> diaries	<input type="checkbox"/> Administered new <input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked <i>- Discuss compliance - <u>Collect</u> and <u>save</u> used medication container with remaining tablets - Do <u>not</u> open container</i>	
6. Study medication in/out (give numbers)	<input type="checkbox"/> Returned: <input type="text"/> containers	<input type="checkbox"/> Administered new: <input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T2 completed	
8. Appointment for next visit	<input type="checkbox"/> Made	
9. Travel cost voucher	<input type="checkbox"/> Given	
10. Completed by: (Name researcher)	
*** END OF T2 VISIT ***		

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CHECKLIST

VISIT AFTER 3 MONTHS - T3

Randomisation number:

VISIT T3 (3 months) CHECKLIST

1. Date visit T3:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y y y</small>	
2. Type of visit	Hospital visit	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked <ul style="list-style-type: none"> - Check the diary days, discuss any unclarities or uncompleted days - <u>Collect</u> and <u>save</u> diary in study file 	
4. Pain diary in/out (give numbers)	<input type="checkbox"/> Returned <input type="text"/> diaries	<input type="checkbox"/> Administered new <input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked <ul style="list-style-type: none"> - Discuss compliance - <u>Collect</u> and <u>save</u> used medication container with remaining tablets - Do <u>not</u> open container 	
6. Study medication in/out (give numbers)	<input type="checkbox"/> Returned: <input type="text"/> containers	<input type="checkbox"/> Administered new: <input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T3 completed	
8. Questionnaire T3 for patient <i>- In case of <u>adults</u> 1 questionnaire</i> <i>- In case of <u>children</u>, 1 questionnaire for parent and 1 for child)</i>	<input type="checkbox"/> Completed	
9. Patient in <u>steady state</u> * for blood sample <i>* No admission painful crisis ≤14 days</i>	<input type="radio"/> No: Postpone bloodsample to T4 <input type="radio"/> Yes: Take blood sample now	
10. Blood sample drawn? (see manual)	<input type="checkbox"/> Drawn	<input type="checkbox"/> Standard lab
		<input type="checkbox"/> Centrifuge / plasma storage
11. Appointment for next visit	<input type="checkbox"/> Made	
12. Travel cost voucher	<input type="checkbox"/> Given	
13. Completed by: (Name researcher)	
*** END OF T3 VISIT ***		

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CHECKLIST

VISIT AFTER 4 MONTHS - T4

Randomisation number:

VISIT T4 (4 months) CHECKLIST

1. Date visit T4:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y y y</small>	
2. Type of visit	<input type="radio"/> <i>By phone</i> <input type="radio"/> <i>Hospital visit</i>	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked <i>- Check the diary days, discuss any unclarities or uncompleted days</i> <i>- <u>Collect</u> and <u>save</u> diary in study file</i>	
4. Pain diary in/out (give numbers)	<input type="checkbox"/> Returned <input type="text"/> diaries	<input type="checkbox"/> Administered new <input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked <i>- Discuss compliance</i> <i>- <u>Collect</u> and <u>save</u> used medication container with remaining tablets</i> <i>- Do <u>not</u> open container</i>	
6. Study medication in/out (give numbers)	<input type="checkbox"/> Returned: <input type="text"/> containers	<input type="checkbox"/> Administered new: <input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T4 completed	
8. Was the T3 bloodsample postponed due to a recent crisis?	<input type="radio"/> No: Skip question 9 and 10 <input type="radio"/> Yes: Continue with question 11	
9. Patient in <u>steady state</u> * for blood sample now? <small>* No admission painful crisis ≤14 days</small>	<input type="radio"/> No: Take sample anyway (make note of recent crisis) <input type="radio"/> Yes: Take blood sample now	
10. Blood sample drawn? (see manual)	<input type="checkbox"/> Drawn	<input type="checkbox"/> Standard lab
		<input type="checkbox"/> Centrifuge / plasma storage
11. Appointment for next visit	<input type="checkbox"/> Made	
12. Travel cost voucher	<input type="checkbox"/> Given	
13. Completed by: (Name researcher)	
*** END OF T4 VISIT ***		

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VISIT AFTER 5 MONTHS - T5

CHECKLIST

Randomisation number:

VISIT T5 (5 months) CHECKLIST

1. Date visit T5:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y y y</small>	
2. Type of visit	<input type="radio"/> <i>By phone</i> <input type="radio"/> <i>Hospital visit</i>	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked <i>- Check the diary days, discuss any unclarities or uncompleted days</i> <i>- <u>Collect</u> and <u>save</u> diary in study file</i>	
4. Pain diary in/out (give numbers)	<input type="checkbox"/> Returned <input type="text"/> diaries	<input type="checkbox"/> Administered new <input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked <i>- Discuss compliance</i> <i>- <u>Collect</u> and <u>save</u> used medication container with remaining tablets</i> <i>- Do <u>not</u> open container</i>	
6. Study medication in/out (give numbers)	<input type="checkbox"/> Returned: <input type="text"/> containers	<input type="checkbox"/> Administered new: <input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T5 completed	
8. Appointment for next visit	<input type="checkbox"/> Made	
9. Travel cost voucher	<input type="checkbox"/> Given	
10. Completed by: (Name researcher)	
*** END OF T5 VISIT ***		

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VISIT AFTER 6 MONTHS - T6

CHECKLIST

Randomisation number:

VISIT T6 (6 months) CHECKLIST

1. Date visit T6:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y y y</small>	
2. Type of visit	Hospital visit	
3. <u>Pain diary</u> completed correctly?	<input type="checkbox"/> Checked	<ul style="list-style-type: none"> - Check the diary days, discuss any unclarities or uncompleted days - <u>Collect</u> and <u>save</u> diary in study file
4. Pain diary in (give number)	<input type="checkbox"/> Returned:	<input type="text"/> diaries
5. Compliance of <u>study medication</u> ?	<input type="checkbox"/> Checked	<ul style="list-style-type: none"> - Discuss compliance - <u>Collect</u> and <u>save</u> used medication container with remaining tablets - Do <u>not</u> open container
6. Study medication in (give number)	<input type="checkbox"/> Returned:	<input type="text"/> containers
7. Study data sheet physician	<input type="checkbox"/> Questions T6 completed	
8. Questionnaire T6 for patient <i>- In case of adults 1 questionnaire - In case of children, 1 questionnaire for parent and 1 for child)</i>	<input type="checkbox"/> Completed	
9. Patient in <u>steady state</u> * for blood sample <i>* No admission painful crisis ≤14 days</i>	<input type="radio"/> No: Take sample anyway (make note of recent crisis) <input type="radio"/> Yes: Take blood sample now	
10. Blood sample drawn? (see manual)	<input type="checkbox"/> Drawn	<input type="checkbox"/> Standard lab
		<input type="checkbox"/> Centrifuge / plasma storage
11. Travel cost voucher	<input type="checkbox"/> Given	
12. Completed by: (Name researcher)	
*** END OF T6 VISIT ***		

SUMMARY STUDY CHECKLIST

1. Total no. of pain diaries returned*Should be 7 in total (6 months, + run-in)* pain diaries**2. Questionnaires completed** T0 T3 T6**3. Blood samples collected** T0 T3 T6***** END OF STUDY *****