(S)AE instructie Hovon 104

Local Investigator:
Onderzoeksverpleegkundige: Miriam Gelderloos 12379
Datamanager: IKNL datamanagement 12177

- Iedere SAE dient **binnen 24 uur** na kennisgeving van de SAE **gemeld** te worden aan de sponsor/opdrachtgever.
- Vul ieder SAE formulier direct en zo zorgvuldig mogelijk in (probeer bij de eerste melding kort, bondig en stellig te formuleren en aannames te vermijden).
- Breng betrokkenen (Local Investigator, onderzoeksverpleegkundige of datamanager) op de hoogte van de SAE melding.
- Het originele SAE formulier dient in de patiëntstatus te worden gearchiveerd.

Op werkdagen kan voor het invullen altijd ondersteuning worden gevraagd aan de (vervanger van de) research-verpleegkundige of datamanager.

FAX: 010 4239014

- Fax de SAE pagina's en alle aanvullende informatie binnen 24 uur

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Studiespecifieke aandachtspunten

Let er op de relatie met de studiemedicatie te vermelden

Relationship	Description
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study medication). There is another reasonable explanation for the event (e.g. the patient's clinical condition, other concomitant treatments)
Possible	There is some evidence to suggest a causal relationship (e.g. the event occurs within a reasonable time after administration of the study medication). However, the influence of other factors may have contributed to the event.(e.g. the patient's clinical condition, other concomitant treatments)
Probable	There is evidence to suggest there is a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a clinical judgment of the causal relationship.

Wat hoeft niet gemeld te worden:

- Opname voor een standaard procedure voor het geven van protocollaire therapie
- Opname vanwege bloed of thrombocyten transfusie
- Opname vanwege protocol/ziekte gerelateerde onderzoeken (bv scans, beenmergpuncties)
- Verlengde opnameduur vanwege technische, praktische of sociale redenen **in afwezigheid van** een adverse event
- Opname vanwege een geplande procedure.

In alle bovenstaande gevallen geld wel dat verlengde opnameduur t.g.v. complicaties van deze procedures wel als SAE gem moeten worden!

HOVON 104 AL AMYLOIDOSIS

SERIOUS ADVERSE EVENT REPORT

Use this form to report all Serious Adverse Events as described in the trial protocol. An **initial report** must be sent to the HOVON Data Center within **24 hours**. Complete information in a first **follow up report** must be reported within **2 days**. The final report is to be sent as soon as outcome of SAE is known. For follow up and final reports you may update the existing initial report.

Fax all 3 pages of the report to: HOVON Data Center, fax +31 (0)10 4239014

Patient information

HOVON Data Center staff only

Patient study number |__|__|__|__|

Sex |__| 1= male 2= female

Date of birth [dd/mm/yyyy] |__||__||_____|

Report information

Site name .....

Country ☐ NL ☐ B ☐ D

Investigator 5 .....

Type of report 7 ☐ Initial report ☐ Follow up report ☐ Final report

Date of initial report [dd/mm/yyyy] 8 |__||__||_____|

Date of follow up report [dd/mm/yyyy] 9 |__||__||_____| |__||__||_____| |__||__||_____|

Date of final report [dd/mm/yyyy] 11 |__||__||_____|

Serious Adverse Event information

Adverse Event Term 12

Diagnosis of Adverse Event in a single term; .....

if no diagnosis is available yet, please provide the most relevant sign or symptom

Date onset AE [dd/mm/yyyy] 13 |__||__||_____|

Date AE became Serious [dd/mm/yyyy] 14 |__||__||_____|

Reason AE is Serious 15 |__| 1= death 2= life-threatening 3= (prolongation of) hospitalization 4= significant / persistent disability 5= congenital anomaly / birth defect 6= other medically important condition

Severity of AE [CTCAE grade] 46 |__|

Highest grade observed

16 **SAE description and comments** - describe the course of events, include dates and results of tests / procedures / actions taken (for final report: outcome of adverse event, test result etc.)

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HOVON 104 AL AMYLOIDOSIS

SERIOUS ADVERSE EVENT REPORT

Fax reports to: HOVON Data Center, fax +31 (0)10 4239014

Pat. Study number: |__|__|__|__| Date of report |__||__||_____|

☐ Initial report ☐ Follow up report ☐ Final report

Trial Medication

Protocol phase during / after which the SAE occurred 18 |__|

0= before start protocol treatment 1= induction cycle1 2= induction cycle 2
3= induction cycle 3 4= induction cycle 4 5= mobilisation 6= HDM/auto-SCT

Bortezomib s.c.

Please specify details of bortezomib s.c. treatment that the patient has received (if not given during this protocol phase, please report last time received)

19 Trial medication[1]	20 Total daily dose (please add units)	22 Date first dose (during this protocol phase)	23 Date last dose (Date last dose prior to SAE)	24 Relationship to SAE[2]	25 Action taken as a result of this SAE[3]
|2|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|

If SAE related (possible, probable, definite) to bortezomib s.c.: **Lot no.** ..... Expiry date |__||__||_____|

Other trial medication

Please specify details of the other trial medication that the patient received in this protocol phase:

19 Trial medication[1]	20 Total daily dose (please add units)	22 Date first dose (during this protocol phase)	23 Date last dose (Date last dose prior to SAE)	24 Relationship to SAE[2]	25 Action taken as a result of this SAE[3]
|1|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|3|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|4|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|5|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|6|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|__|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|__|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|
|__|	.....	|__||__||_____|	|__||__||_____|	|__|	|__|

[1] Trial medication	[2] Relationship to SAE	[3] Action taken
1= dexamethasone p.o. 5=melphalan i.v. 2= bortezomib s.c. 6=auto-SCT 3= G-CSF 4=cyclophosphamide	0= unrelated 1= unlikely 2= possible 3= probable 4= definite	0= none 1= next dose reduced 7 = drug withdrawn (temporarily or permanently) 6= not applicable

HOVON 104 AL AMYLOIDOSIS

SERIOUS ADVERSE EVENT REPORT

Fax reports to: HOVON Data Center, fax +31 (0)10 4239014

Pat. Study number: |__|__|__|__| Date of report |__||__||_____|

☐ Initial report ☐ Follow up report ☐ Final report

34 Possible Causes of SAE other than bortezomib s.c. and other Trial medication(s)

please specify if there are circumstances other than trial medication that may have contributed to the SAE or could help explain the SAE

Disease under study (including progression)	47	|__|	0= No 1= Yes
Disease under study could help explain the SAE or may have caused the SAE			
Medical condition(s)	48	|__|	0= No 1= Yes, specify below
Any relevant past or current medical disorders (not disease under study), allergies, surgeries that could help explain the SAE			
Concomitant medication(s)	49	|__|	0= No 1= Yes, specify below
Any relevant concomitant medication(s) that could help explain the SAE or may have caused the SAE			
Trial related procedure(s) (*e.g. placing IV line or bone marrow/fat biopsy*)	50	|__|	0= No 1= Yes, specify below
Other	51	|__|	0= No 1= Yes, specify below

Specification:.....

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Outcome of SAE

Outcome of SAE 35 |__|

1= resolved*
3= ongoing
4= death *(caused by SAE)***
5= ongoing at death *(death due to another cause)***
6= ongoing closed *(because stable situation reached)*

* Date SAE resolved [dd/mm/yyyy] 36 |__||__||_____|

** Date of death [dd/mm/yyyy] 39 |__||__||_____|

** Cause of death 40 .....

Signatures – the (sub) investigator should always review and sign at least the final report

Report	Name reporter	Function	Date	Signature
Initial	.....	.....	|__||__||_____|	.....
Follow up	.....	.....	|__||__||_____|	.....
Follow up	.....	.....	|__||__||_____|	.....
Follow up	.....	.....	|__||__||_____|	.....
Final	.....	**(sub) investigator**	|__||__||_____|	.....

HOVON Data Center staff only

SAE sequence number 2 |__|__|

Initial report reviewed by (initials) ..... Date review |__||__||_____|

Follow up report reviewed by (initials) ..... Date review |__||__||_____|

Final report reviewed by (initials) ..... Date review |__||__||_____|