

Pleurodesis Therapy with Viscum album (Mistletoe)

Case documentation sheet



Stamp of the examining doctor

Pat.-Initials:
First Name Surname

Pat.-No.:



Initials:

Firstn.
Surn..

Pat.-No.:

Today's Date:

Day
Month
Year

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Pleurodesis documentation

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1.1 Basic documentation

Date of birth

Day

Month

Year

Sex

M F

Height (cm)

Weight (kg)

Karnofsky score at the beginning of mistletoe pleurodesis: _____ % (see appendix page 1/3)

Type of documentation: retrospektiv 1 Prospektiv 2 retro-/prospektiv
prospektiv
since: _____

2.1 Tumour diagnosis

Diagnosis _____

Initial diagnosis

Month

Year

Tumorstate at initial
diagnosis _____

Current tumorstate

p T N M

or

UICC-class. I II III IV

Other classification _____

Current metastasis:*

 PUL OSS HEP BRA LYM MAR PLE PER ADR SKI SPL GEN

Other: _____

Histology _____

Grading (I – III) _____

Hormone receptors

 negative positive: _____ % / _____ %
oestrogen-recpt. progesteron-recpt.

Herceptin-receptors

 negative positive _____ %

* short code Metastasis: PUL = pulmo, OSS = bone, HEP = liver, BRA = brain, LYM = lymphnode, MAR = bone marrow, PLE = pleura, PER = peritoneum, ADR = suprarenal, SKI = skin, SPL = spleen, GEN = general metastasis

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1.3 Patient anamnesis (other than pleural effusion, see 3.1)

none

Concomitant illnesses, previous operations etc.

(such as Diabetes mellitus since 1984, and coronary heart disease since 1995)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

1.4 Current concomitant medication

none

(other than for tumour therapy, see 2.2)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

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2.1 Tumour therapy *prior to* mistletoe pleurodesis

none

Type of therapy	Exact description incl. dates (from – until)	Therapy success (according to WHO*)
<p>Operation</p> <p>(OP-description)</p> <p><input type="checkbox"/> none</p>	<p>(such as total excision of breast cancer)</p>	
<p>Radiation</p> <p>(Radiation field, radiation dose)</p> <p><input type="checkbox"/> none</p>	<p>(such as percutaneous rad., 50 Gy)</p>	
<p>Chemotherapy</p> <p>(schedule, drug, no. of cycles)</p> <p><input type="checkbox"/> none</p>	<p>(such as CMF, 6 cycles)</p>	
<p>Hormone therapy</p> <p><input type="checkbox"/> none</p>	<p>(such as MPA)</p>	
<p>Immune therapy</p> <p><input type="checkbox"/> none</p>	<p>(such as Interferon)</p>	
<p>Other therapies</p>	<p>(such as Thyme, Echinacea; mistletoe see 4.1)</p>	

*Complete Remission = CR; Partial Remission = PR (remission \geq 50% for at least four weeks); Disease unchanged = NC (remission $<$ 50% or no change in size or increase $<$ 25%); progression = PD (increase $>$ 25% or new tumour manifestation).

Pleurodesis documentation

Initials:

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Today's Date:

Day

Month

Year

2.2 Tumour therapy *during/after* mistletoe pleurodesis none

Type of therapy	Exact description incl. date (from – until)	Therapy-success (according to WHO*)
<p>Operation</p> <p>(OP-description)</p> <p><input type="checkbox"/> none</p>		
<p>Radiation</p> <p>(Radiation field, radiation dose)</p> <p><input type="checkbox"/> none</p>	<p>(such as percutaneous rad., 50 Gy)</p>	
<p>Chemotherapy</p> <p>(Schedule, type of drug, no. of cycles)</p> <p><input type="checkbox"/> none</p>	<p>(such as CMF, 6 cycles)</p>	
<p>Hormone therapy</p> <p><input type="checkbox"/> none</p>	<p>(such as MPA)</p>	
<p>Immune therapy</p> <p><input type="checkbox"/> none</p>	<p>(such as Interferon)</p>	
<p>Other therapies</p>	<p>(such as Thyme, Echinacea; mistletoe see 4.1)</p>	

*Complete Remission = CR; Partial Remission = PR (remission \geq 50% for at least four weeks); Disease unchanged r = NC (remission $<$ 50% or no change in size or increase $<$ 25%); progression = PD (Increase $>$ 25% or new tumour manifestation).

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3.1 Characterisation of the pleural effusion

Initial diagnosis:

Month

Year

Localisation:

 right

 left

via

 Clinic

 Ultrasound scan

 Chest X-ray

 CT

 MRI

Symptoms depending on effusion

 Dyspnea

 Cough

 Pleural pains

 Others _____

Is there a pericardial effusion as well?

 no

 yes

Examination of pleural fluid (if present)*:

Puncture (date):	1. <input type="text"/> <input type="text"/> Day Month	2. <input type="text"/> <input type="text"/> Day Month	3. <input type="text"/> <input type="text"/> Day Month	4. <input type="text"/> <input type="text"/> Day Month
Cytology				
Total protein in pleural fluid				
Total protein in serum				
LDH in pleural fluid				
LDH in serum				
Immunological parameters				
Mistletoe lectin antibodies				
Other				

* see appendix transudate/exudate; please hand in copies of the original results as appendix

Pleurodesis documentation

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Day Month Year

3.2 Therapy of the pleural effusion prior to mistletoe pleurodesis

none

- Thoracoscopy Drainage without pleural installation (Bülau, Matthys-Katheter)
- One off pleurocentesis Drainage with pleural installation (Bülau, Matthys-Katheter)
- Intrapleural therapy with other pleurodetics prior to mistletoe pleurodesis

Please insert therapies in table with date:

Preparation	Dose of the preparation	Date	Thoraco-scopy	Catheter (Bülau, Matthys-K.) from - until	One off puncture	Effusion (ml)
1.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
2.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
3.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
4.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
5.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
6.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
7.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
8.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
9.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
10.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
11.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				
12.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>Day Month Year</small>				

Please insert available results of laboratory chemical examination of pleural fluid on page 7.

Pleurodesis documentation

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Today's Date:

Day Month Year

3.3 Mistletoe pleurodesis

Mistletoe preparations:

Abnoba viscum _____
Host tree

Helixor A M P

Iscador _____
Host tree

Other mistletoe prep.: _____

Please insert therapies in table with date:

Treatment No.	Dose of the mistletoe-preparation (mg or stage)	Date	Thoraco-scropy	Catheter (Bülau, Matthys-K.) from - until	One off puncture	Effusion (ml)
1.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
2.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
3.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
4.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
5.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
6.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
7.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
8.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
9.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
10.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
11.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				
12.		<input type="text"/> <input type="text"/> <input type="text"/> Day Month Year				

See example of mistletoe pleurodesis appendix page 2/3.

Please insert available results of laboratory chemical examination of pleural fluid on page 7.

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4.2 Reactions to systemic mistletoe therapy

 none

Local infection At what dose _____ Height in cm _____

Side effects: _____

Temperature reactions:
Over what period of time _____
At what dose _____
What type of application _____

Laboratory changes during therapy*:
(Complete blood count, CRP, immune status):

*Please include copies of original results in appendix

General reactions after injection:
(z. B. Tiredness, exhaustion, shivering, aching limbs, dizziness, skin rash)

Others:

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5.1 Assessment of mistletoe pleurodesis

According to WHO guidelines:

- CR Complete remission: No further effusion can be detected within four weeks of last pleurocentesis
- PR Partial remission: A further effusion occurs within four weeks of the last pleurocentesis but does not require a further pleurocentesis
- NC/PD No success: A further effusion occurs within four weeks of last pleurocentesis and requires pleurocentesis.
- Therapy outcome could not be recorded according to WHO criteria.
because: patient has died patient cannot be contacted
other: _____ _____

According to the doctor in charge of the treatment, is:

1. Pleurodesis therapy with mistletoe:

- very easy often easy quite difficult very difficult

2. Are the ADRs of prime concern during therapy?:

- very sometimes rarely never

3. For the patient, pleurodesis therapy has been

- very good good moderately good bad

Free space for therapy assessment:

Karnofsky Performance Scale:

A		B		C	
%	Comment	%	Comment	%	Comment
	Normal activity. No special care required.		Unable to work, can live at home and care for self but requires help with certain activities.		Patient cannot look after self. Patient requires special assistance and medical care.
100	Normal state. No complaints. No evidence of disease.	70	Patient is able to care for self, but is unable to carry out normal activities or active work.	40	The patient is disabled and requires special care and assistance.
90	Capable of normal activities. Minor signs/symptoms.	60	Patient is able to care for self, but requires occasional assistance-	30	Patient is severely disabled and hospitalisation is necessary. Death is not imminent.
80	Some signs/symptoms and patient requires some effort to carry out normal activities.	50	The patient requires medical care and much assistance with self care.	20	The patient is very ill with hospitalisation and active life-support treatment required.
				10	Moribund. Fatal process proceeding rapidly.

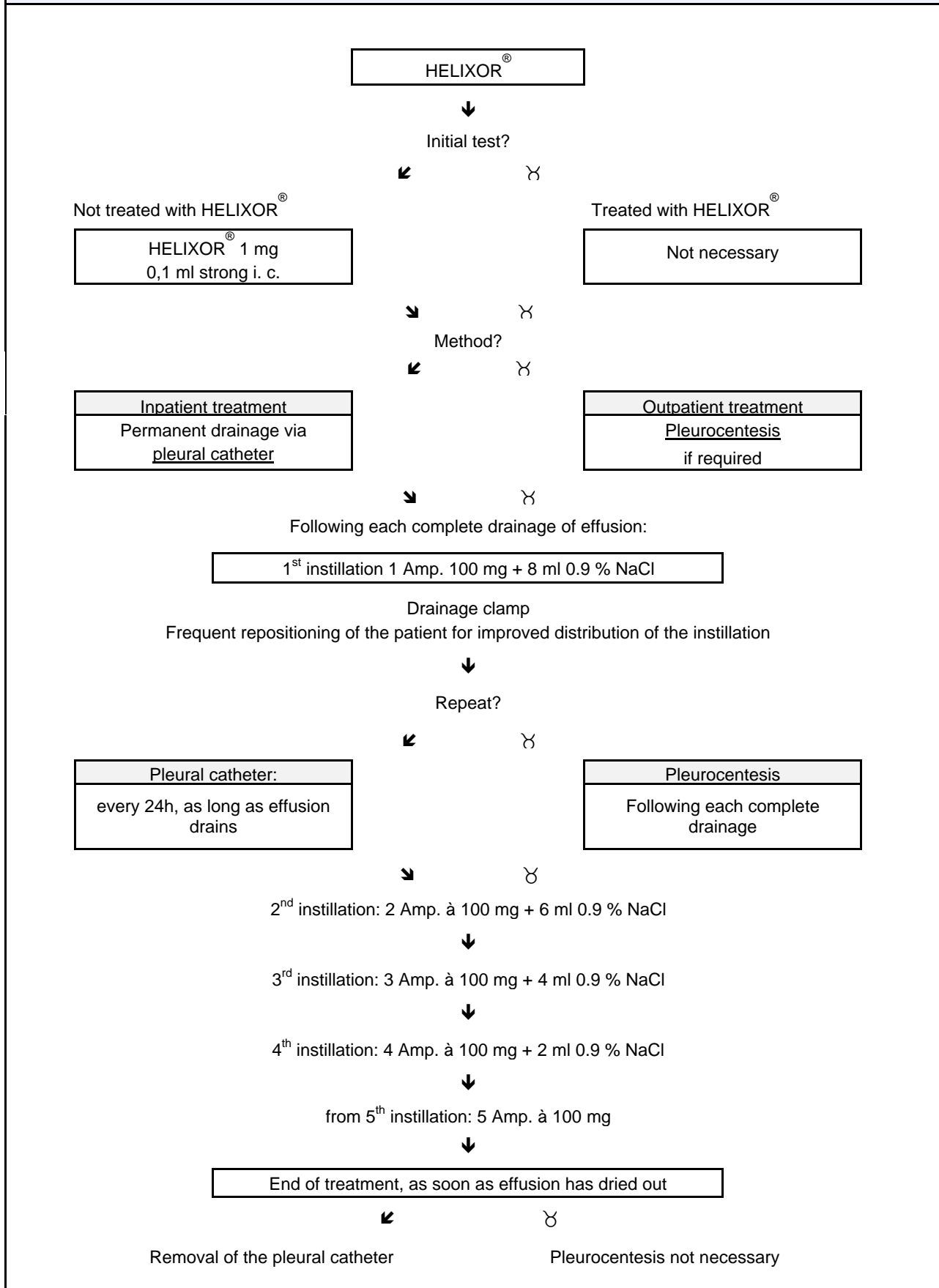
Differentiation of the pleural effusion in transudate and exudate
(Modified according to Loddenkemper 1992)

Parameter	Transudate	Exudate
Total protein	< 30 g	> 30 g
GE-Pleura/GE-Serum	< 0,5	> 0,5
Specific weight	< 1016	> 1016
Lactate dehydrogenases	< 200 U/l	> 200 U/l
LDH-PI / LDH-Serum	< 0,6	> 0,6
No. of leukocytes	< 1000/ml	>1000/ml
No. of erythrocytes	< 10000/ml	> 10000/ml
Cholesterol	< 60 mg/dl	> 60 mg/dl
Bili-PI/Bili-Serum	< 0,6	> 0,6

Degrees of severity and therapy for allergic reaction:

Clinic	Therapy
<p>Grade I local reaction</p> <p>Edema, erythema, pruritus, wheals, Quincke's edema</p>	<ul style="list-style-type: none"> - Stop allergen exposure - Antihistamines such as Fenistil 4 mg (Dimetinden) or Tavegil 2 mg (Clemastin) i.v. - H2-Blockers such as Tagamet 400 mg (Cimetidin) i.v.
<p>Grade II Systemic reaction</p> <p>Additional nausea, vomiting, onset of bronchospasms tachycardia, falling blood pressure</p>	<ul style="list-style-type: none"> - Supply of oxygen - Infusion of 500 – 1000 ml Ringer's solution - 250 mg Solu-Decortin H (Prednisolon) - possibly beta2-mimetics (for inhalation)
<p>Grade III Severe systemic reaction</p> <p>Additional shock Severe bronchospasms Coma</p>	<ul style="list-style-type: none"> - Volume substitution with Ringer's solution, preferably also Haes 6/10% - Adrenaline 0,1-1 mg i.v., repeat after 3 min. - Solu-Decortin 1000mg or Fortecortin 100mg - 1 Amp. Theophyllin 0,24 g over 10 mg - 5-10 mg Diazepam (if fear of suffocation) with larynx- or glottis edema
<p>Grade IV</p> <p>Respiratory arrest, circulatory collapse</p>	<ul style="list-style-type: none"> - Reanimation

Sample case - mistletoe pleurodesis with HELIXOR®:



Notes:

This documentation sheet was developed at the Forschungsinstitut Havelhöhe (FIH) Berlin, and kindly supported by Helixor Heilmittel GmbH & Co. For interest it is free available on demand (see addresses) or see for downloading (pdf-file) www.fih-berlin/pleurodese.de. Comments or questions are welcome at mistelpleurodese@fih-berlin.de .

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