Erasmus MC
Universitair Medisch Centrum Rotterdam

THE DESMOID TUMOR RESEARCH FOUNDATION

GRAFITI
DESMOID | RESEARCH

Desmoïd Tumor Research Foundation (DTRF) annual meeting

Philadelphia, September 23 & 24, 2017

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Introduction

Recurrence rates after treatment up to 69%[11,15,16]

Progressive disease < 2 yrs[13,14,15]

Wait & See policy for aggressive fibromatosis (AF)

Spontaneous regression 5-28% cases[12,14]

Adverse treatment effects

1. Crago et al. Ann of Surg, vol 258: 2, 347-353 ,2013
2. Salas et al. J Clin Oncol, 29: 3553-3558, 2011
3. Fiore et al. Ann Surg Oncol, 16:2587-2593, 2011
4. Bonvalot et al. Ann Surg Oncol, 20:4096-4102, 2013
5. Rock et al. J Bone Joint Surg Am, 66:1369-1374, 1984
6. Ballo et al. J Clin Onocol, 17:158-167,1999

GRAFITI

Growth of **a**ggressive **fi**bromatosis without **t**herapeutic **i**ntervention

GRAFITI

GRAFITI


umcg


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GRAFITI

Start study: May 2014

Study design: prospective observational study

Study population: patiënts diagnosed with aggressive fibromatosis (AF) with extra-abdominal or abdominal wall tumor localization

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Primairy endpoint: tumor progression (RECIST)

Progression **= ≥ 20%** of the sum of the **longest diameter**, in comparison with the **smallest sum of the longest diameter** since the time of inclusion.

Secondary endpoint: quality of life (QOL) during the W&S policy.

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Additional goals

Evaluate willingness of patients for a W&S policy

Analyze factors for the prediction of progression

Evaluate considerations for switch to active treatment

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Study goal: 100 patiënts

Inclusion rate: 62*

* 01-09-2017

Criteria

Inclusion criteria	Exclusion criteria
extra-abdominal and abdominal wall AF	age < 18 years
histologically proof of AF	medical / family history of FAP*
able to receive a MRI-scan	intra-abdominal tumor
No functional limitations due to the tumor	potentially life-threatening tumor
understand and sign informed consent	severe functional limitation in case of progression
	unavoidable mutilation in case of progression
	severe pain associated with the tumor
	local or systemic therapy for the current manifestation of AF

*familial adenomatous polyposis (FAP)

Follow-up

	Inclusion	Year 1				Year 2		Year 3		
Months		3	6	9	12	18	24	36	48	60
Medical history and physical examination	x	x	x	x	x	x	x	x	x	x
MRI-scan	x		x		x		x			
Ultrasound	x	x		x		x			x	x
EORTC qlqc-30 questionnaire	x		x		x		x			x

Interim analysis

Inclusion of the **first 20 patiënts,** with **complete** 1 year follow-up

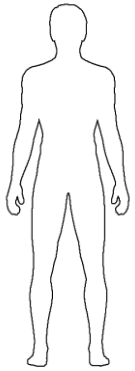
Continuing the GRAFITI:

> 50% has to have a W&S policy 1 year after inclusion

Patient characteristics I

15:5

median 12 weeks (range 1- >104 weeks)



extremity	7 (35%)
abdominal wall	6 (30%)
thorax	4 (20%)
head / neck	1 (5%)
back	2 (10%)

solitary lesion	17 (85%)
multiple lesions	3 (15%)

Patient characteristics II

tumor growth	yes	11 (55%)
	no	8 (40%)
	unknown	1 (5%)

Patient characteristics II

tumor growth	yes	11 (55%)	0-2 cm / month	6 (55%)
	no	8 (40%)	2-5 cm/ month	1 (9%)
	unknown	1 (5%)	not specified	4 (36%)

median size at palpation 3 cm (range 0-10 cm)

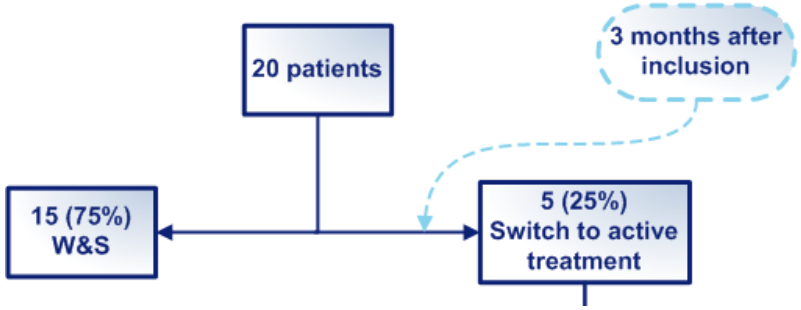
Patient characteristics III

VAS*	Inclusion	3 M	6 M	9 M	12 M
1-4 mild pain	14 (70%)	11 (55%)	8 (40%)	8 (40%)	7 (35%)
5-6 moderate pain	1 (5%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)
7-10 severe pain	0	2 (10%)	1 (5%)	1 (5%)	0
unknown	4 (20%)	6 (30%)	5 (25%)	5 (25%)	7 (35%)

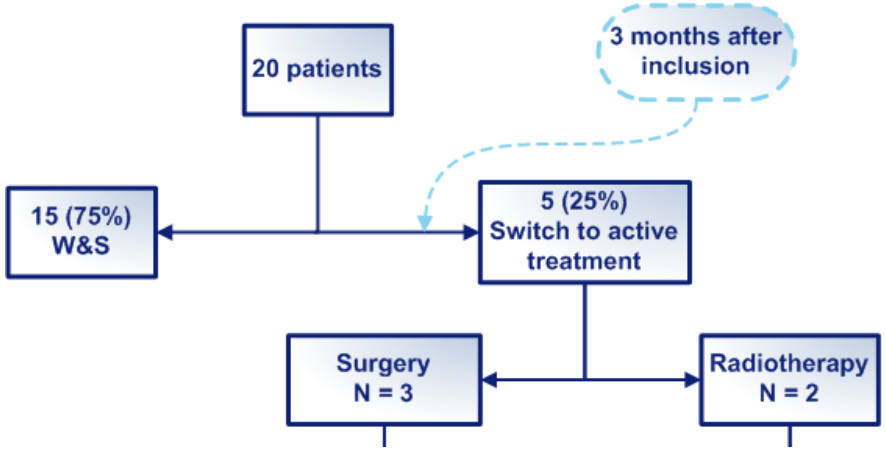
symptoms					
none	7 (35%)	9 (45%)	8 (40%)	5 (25%)	5 (25%)
sensory	6 (30%)	6 (30%)	3 (15%)	4 (20%)	7 (35%)
motoric	1 (5%)	1 (5%)	0	0	0
other**	5 (25%)	3 (15%)	2 (10%)	2 (10%)	0
unknown	1 (5%)	1 (5%)	2 (10%)	4 (20%)	0

* Visual Analog Scale (VAS)
** Heavy feeling, stabbing pain, pain at sports, pain at abdominal pressure, heavy menstruation, very minor pain, minor motoric limited function

Results


20 patients
3 months after inclusion
15 (75%) W&S
5 (25%) Switch to active treatment

Results


20 patients
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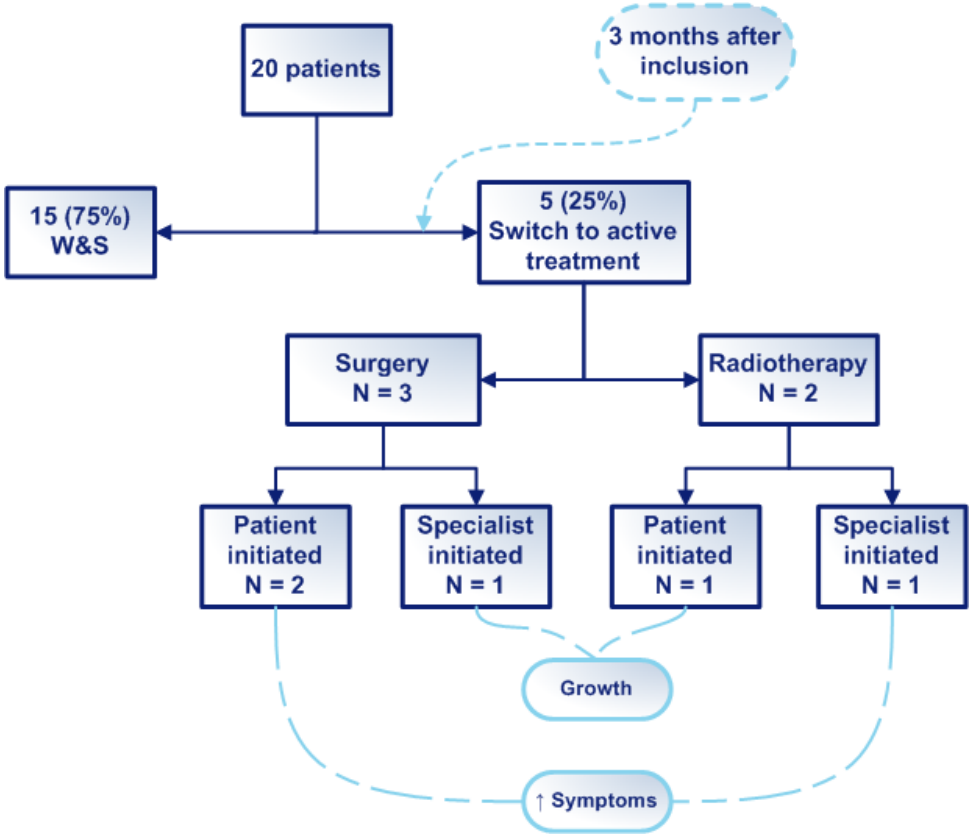
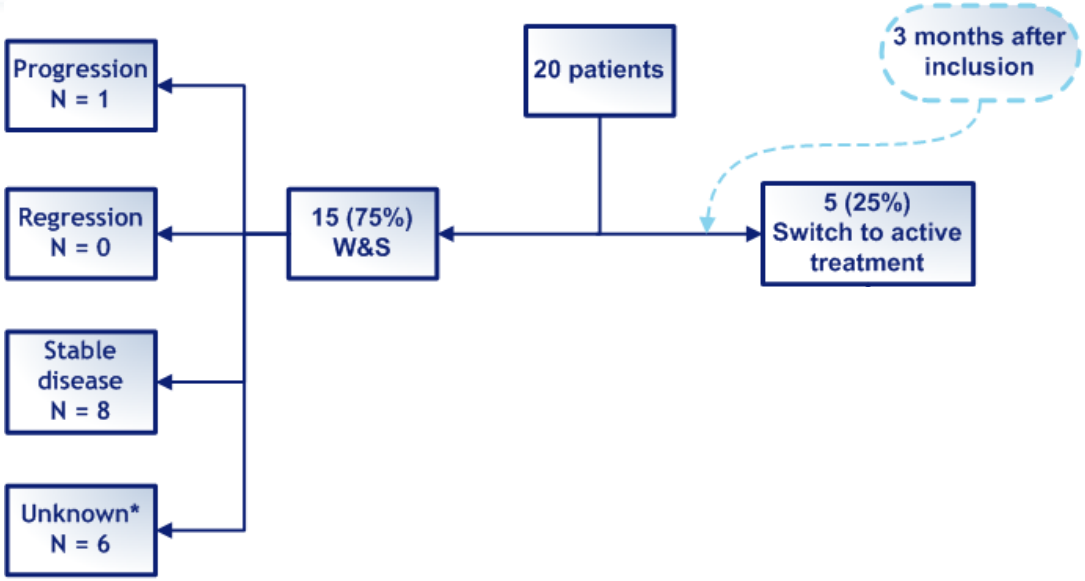
Surgery N = 3
Radiotherapy N = 2

Results


20 patients
3 months after inclusion
15 (75%) W&S
5 (25%) Switch to active treatment
Surgery N = 3
Radiotherapy N = 2
Patient initiated N = 2
Specialist initiated N = 1
Patient initiated N = 1
Specialist initiated N = 1
Growth
↑ Symptoms

Results



** No measurements available*

Switch to active treatment

		N = 5
sex	male female	1 4
median age		22 years (19-33 years)
medical history of prior desmoid	no yes	3 2
localization	extremity abdominal wall back	2 2 1
surgery at tumor site	no yes	2 3
number of tumors	solitary	5

Conclusion - I

> 50% of patiënts with AF continue a W&S policy in the GRAFITI study

It is **safe** to continue the GRAFITI study.

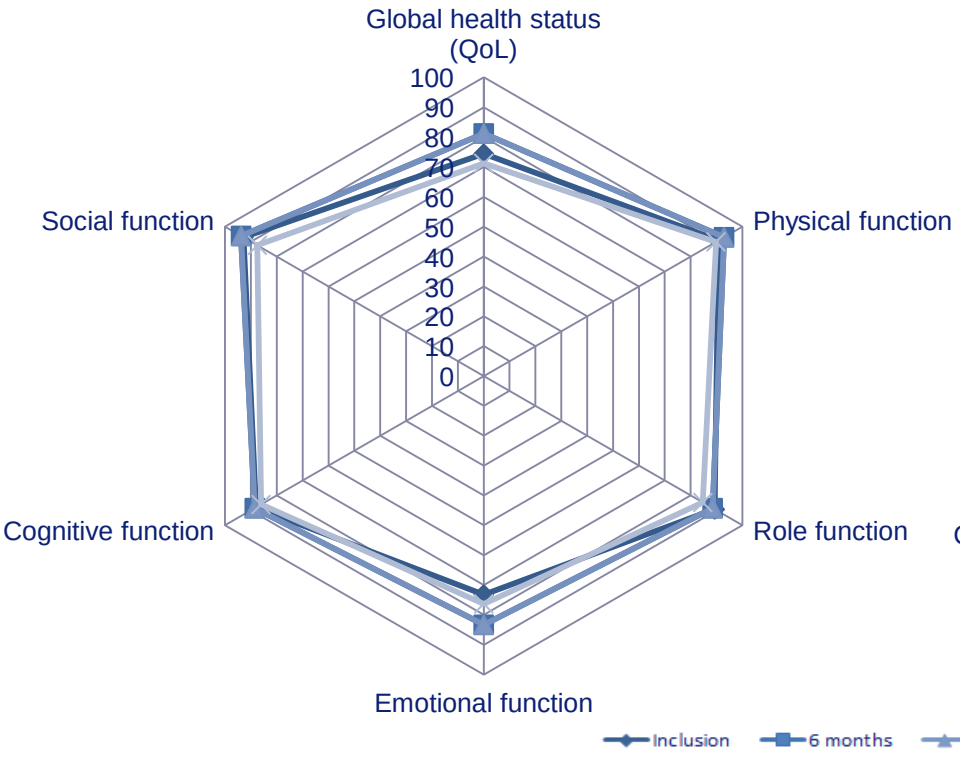
Quality of life

QOL	functional scales	symptom scales	single items
global health status	physical functioning	fatigue	dyspnoea
	role functioning	nausea and vomiting	insomnia
	emotional functioning	pain	appetite loss
	cognitive functioning		constipation
	social functioning		diarrhoea
			financial difficulties

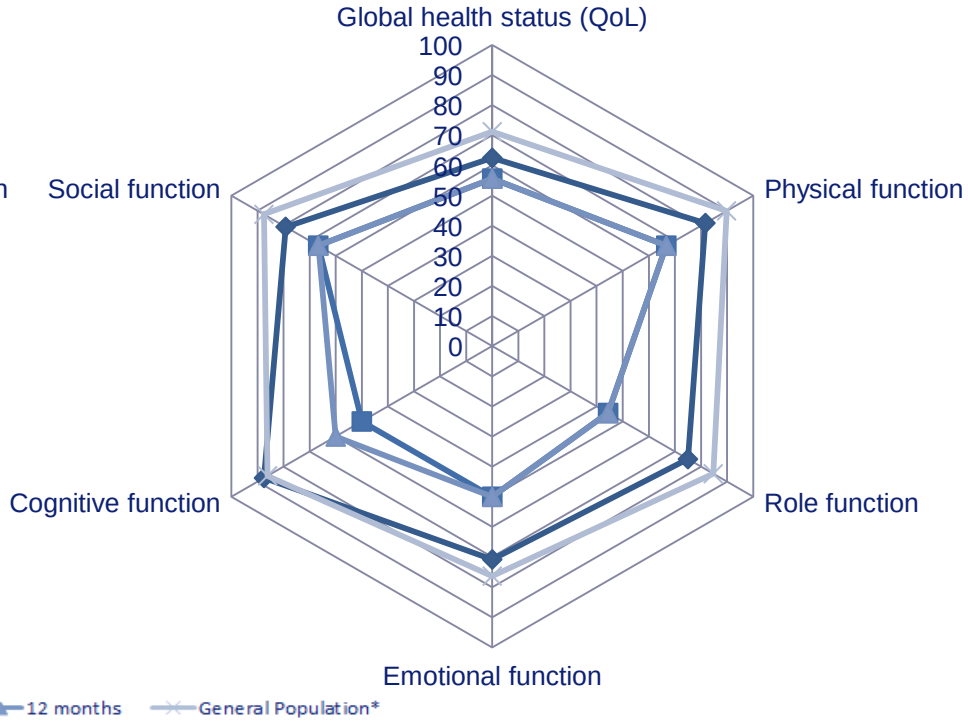
Measured by EORTC QLQ-c30 questionnary

Quality of life

W&S



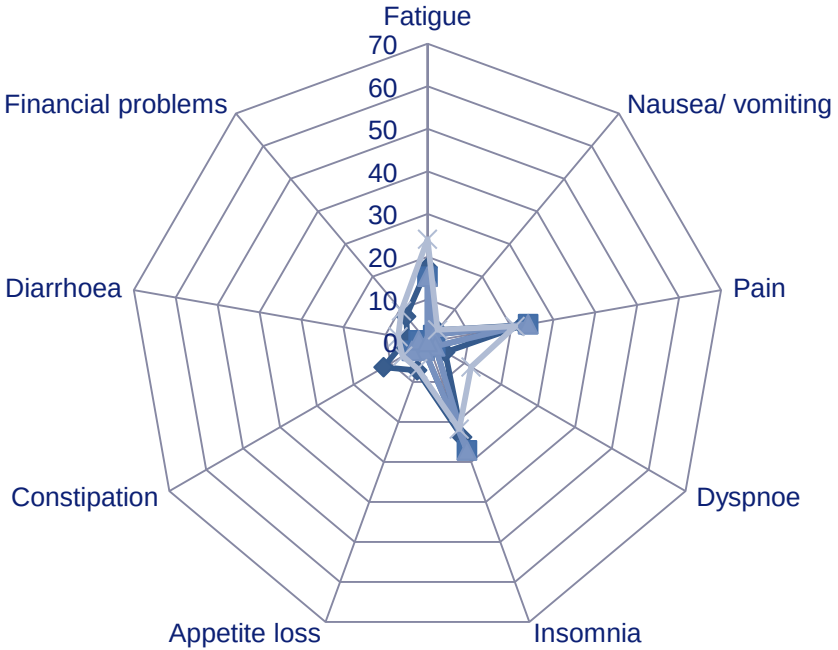
Switch to active treatment



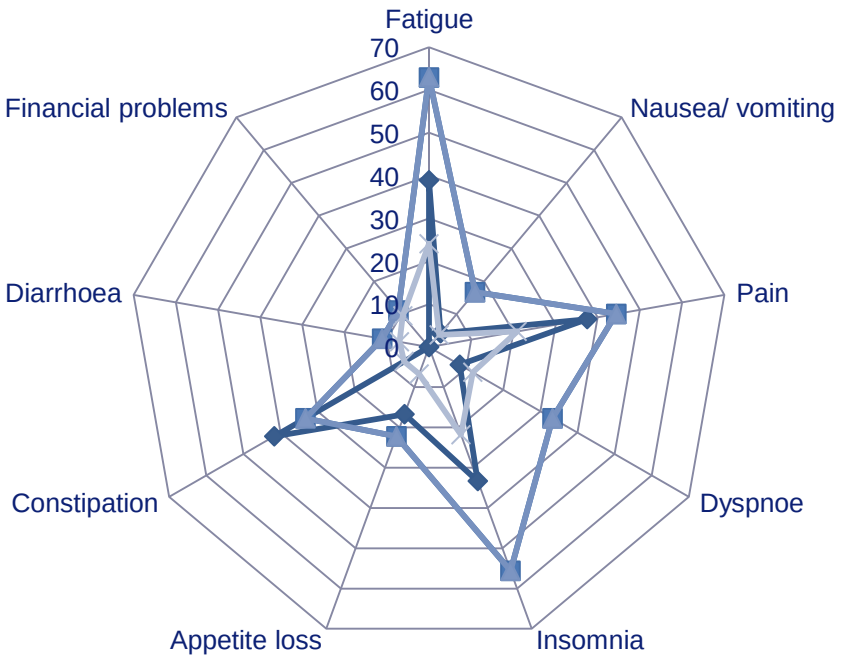
** Data obtained from EORTC reference values manual*

Quality of life

W&S



Switch to active treatment



Inclusion | 6 months | 12 months | General Population*

** Data obtained from EORTC reference values manual*

Conclusion - II

It is **safe** to continue the GRAFITI study.

QOL in the W&S group is comparable to the QOL measured in the general population

Questions?

Thank you for your attention

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