1. Introduction

This guideline provides information on the use of Thymoglobuline® (rabbit anti-human thymocyte immunoglobulin or r-ATG) in the Leicester transplant unit for the treatment of steroid resistant graft rejection in renal transplantation.

2. Scope

This guideline has been developed for use by registered nurses, pharmacists and doctors to prescribe, order and administer r-ATG to kidney transplant patients. Clinical guidelines are 'guidelines' only. The interpretation and application of clinical guidelines will remain the responsibility of the individual practitioner. If in doubt consult a senior colleague or expert.

3. Guideline Standards and Procedures

- 3.1. Supply and Storage
 - r-ATG must always be kept refrigerated (between 2 and 8°C). Once reconstituted, r-ATG
 has an expiry of 24 hours and should be administered within that time limit (including the
 infusion time).
- 3.2. Prescribing and administration
 - r-ATG must be prescribed on the r-ATG prescription and monitoring chart (see Appendix 1) AND in the patient's Nervecentre Medication chart.
 - The treatment dose of r-ATG is 1.5 mg/kg/day (rounded to the nearest 25 mg vial) given for a total of 10-14 days. Most patients will receive r-ATG every 2-4 days depending on their clinical condition and WBC, platelet and lymphocyte counts.
 - Dose adjustments:
 - Reduce r-ATG dose by 50% if the total platelet count < 80 x 10 /L or the total WCC is < 2.5 x 10/L
 - Do not administer r-ATG if the total platelet count < 50 x 10 /L, or the WCC < 1.5 x 10 /L or the total lymphocyte count < 0.05 x 10 /L
 - All patients will receive the following pre-medication 1 hour before each dose of r-ATG they need prescribing on NerveCentre:
 - Paracetamol 1g PO
 - Chlorphenamine 4mg PO
 - Hydrocortisone 100mg IV
 - r-ATG is diluted in 500mL of sodium chloride 0.9% and infused via a central line over at least 6 hours.
 - Severe r-ATG associated cytokine release syndrome (CRS) can lead to fatal pulmonary oedema. All patients must have a fluid assessment before receiving r-ATG. This will be done by a senior clinician to ensure patients are not fluid overloaded.
 - r-ATG must be given during core working hours and life support measures are readily available due to its side- effect profile (including severe anaphylaxis). Subsequent doses will also be given during core working hours unless instructed otherwise by the leading clinician on duty. Patients being treated with r-ATG must have all other

immunosuppression stopped (prednisolone is usually continued but this is the only exception). Oral immunosuppression therapy (calcineurin inhibitors and antiproliferative agents) should be re-started 48 hours before the last dose of r-ATG and levels monitored and acted upon.

3.3. Adverse Effects

- In rare instances, serious immune-mediated reactions have been reported with the use of r-ATG and consist of anaphylaxis (could be fatal) or CRS, which has been associated with cardiorespiratory dysfunction (including hypotension, ARDS, pulmonary oedema, myocardial infarction, tachycardia, and/or death).
- Severe, acute infusion-associated reactions (IARs) are consistent with CRS which is attributed to the release of cytokines by activated monocytes and lymphocytes. IARs may occur following the administration of r-ATG. Such reactions may occur as soon as the first or second dose. Clinical manifestations of IARs have included some of the following signs and symptoms: fever, chills/rigors, dyspnoea, nausea/vomiting, diarrhoea, hypotension or hypertension, malaise, rash, and/or headache.
- r-ATG must be used only under strict medical and nursing supervision (see r-ATG chart for more details) in an area with readily available life support equipment. If an anaphylactic or acute infusion reaction occurs, the infusion should be stopped immediately and appropriate emergency treatment should be initiated.

3.4. CMV prophylaxis

- Patients that have been treated with r-ATG may need prophylaxis against CMV and PJP infections.
- A 3 month course of oral valganciclovir is given to all patients treated with r-ATG unless BOTH the donor and recipient are CMV IgG negative. Valganciclovir doses are adjusted according to the patient's creatinine clearance using the Cockcroft and Gault formula.
- All patients will receive a 6 month course of oral co-trimoxazole (480 mg daily). If they are allergic to either trimethroprim or sulfamethoxazole, patients will receive a 6 month course of oral atovaquone (750 mg bd). PJP prophylaxis must be prescribed on discharge to minimise the risk of myelosuppression if given concomitantly with r-ATG.

4. Education and Training

None

5. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency
Number of patients treated with r-ATG per year	JAC report, medical notes review	Amy Page	Annually
Number of patients that received CMV prophylaxis after r-ATG	JAC report, medical notes review	Amy Page	Annually

6. Supporting References (maximum of 3)

Thymoglobuline® 25 mg powder for solution for infusion - Summary of Product Characteristics. Genzyme. Last revision: 3 May 2015. Available on the electronic medicines compendium (eMC) at www.medicines.org.uk. Accessed on 31/03/2016.

7. Key Words

ATG, thymoglobuline, rejection, kidney transplant

CONTACT AND REVIEW DETAILS						
Guideline Lead (Name and Title)	Executive Lead					
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Details of Changes made during review:

April 2022 - Added r-ATG administration and monitoring chart, removed aseptic preparation at LRI pharmacy laboratory to reflect preparation and administration on the transplant ward.

November 2024 - Minor amedments of style and form, but contents remain unchanged

Appendix 1 - PRESCRIBING, ADMINISTRATION AND MONITORING

Drug Sensitivities

Date recorded	Drug(s)	Reaction

Patient's details	P	ati	ier	ıt's	d	eta	ail	s
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Patient name	
Hospital number	
Date of birth	
Address	

The treatment dose of r-ATG is 1.5 mg/kg/day (rounded to the nearest 25 mg vial) given for a total of 10-14 days based on WBC, platelet and lymphocyte counts. See dose adjustments below:

- **Reduce r-ATG dose by 50%** if the total platelet count $< 80 \times 10^9 / L$ or the total WBC is $< 2.5 \times 10^9 / L$
- **Do not administer r-ATG** if the total platelet count < 50×10^9 /L, or the WBC < 1.5×10^9 /L or the total lymphocyte count < 0.05 x 10⁹/L

Patient's weight

Date					
Weight (Kg)					
Date					
Weight (Kg)					

Blood results

Date	Cr	К	Hb	WBC	Platelet count	Lymphocyte count	

THYMOGLOBULINE (r-ATG) CHART

	Patient name					
	Hospital number					
	Date of birth					
	Address					
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ndication for the us	e of r-ATG (please include bio	psy finaings o	ina otnei	reievant	ciinicai aetaiis)	
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Patient's details

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Patient's name:	S number:	Date of birth:

THYMOGLOBULINE (r-ATG) CHART

1st THYMOGLOBULINE (r-ATG) INFUSION

Date	Time	Premedication drugs	Route	Dose	Signature/ print name	Time Given	Given by/Checked by Sign/Print name
		Paracetamol	oral	1g			
		Chlorphenamine	oral	4mg			
		Hydrocortisone	iv	100mg			
Start AT	G 1 hou	r after administration of pr	emedicati	ion drugs			·
		r-ATG in 500mls of sodium chloride 0.9%*	iv				

^{*} Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours and life support measures are readily available due to its side-effect profile (including severe anaphylaxis).

	Start r- ATG	15 min	30 min	45 min	1 h	75 min	1.5 h	105 min	2 h
Time									
ВР									
Pulse									
Respiratory rate									
Temp (°C)									
Oxygen saturation (%)									
		ı	ı						
	2.5 h	3 h	3.5 h	4 h	5 h	6 h	7 h	8 h	9 h **
Time									
ВР									
Pulse									
Respiratory rate									
Town (9C)									
Temp (°C)									

^{**}Follow EWS chart recommendations for further observations frequency.

Any other patient observations									

Oxygen saturation (%)

THYMOG	LOBULINE
(r-ATG	CHART

Date Time Start ATG 1 h Infuse over aupport measurement of the second	hour a	Premedication Paracetamol Chlorphenamic Hydrocortison after administr r-ATG in 500 sodium chlori ast 6 hours via are readily ava Start r- ATG	ne e ration of poors de 0.9%*	remedicativ	must be a		ne G	g core work		ame
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Time BP Pulse Respiratory ra Temp (°C) Oxygen satura	hour a	Hydrocortison after administr r-ATG in 500 sodium chlori ast 6 hours via are readily ava	e ration of promise of de 0.9%* central linidable due	iv remedica iv ne. r-ATG to its side	100mg tion drugs must be a	ofile (includ	ding sev	ere anaphyla	ixis).	
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ВР										
Pulse										
Respiratory ra	rate									
Temp (°C)										
Oxygen satura	ration	(%)								
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Any other p	patie	nt observation	ons							

THYMOG	LOBULINE
(r-ATG	CHART

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		Chlor	phenamir	ne	oral	4mg						
			ocortisone		iv	100mg						
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			ATG in 500 um chloric		iv							
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Pulse												
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Temp (°C		(O/)										
Oxygen s	aturatio	n (%)										
			2.5 h	3 h	3.5 h	4 h	5 h	6 h		7 h	8 h	9 h **
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ВР												
Pulse												
Respirato												
Temp (°C												
Oxygen s	aturatio	n (%)										
					further o	bservation	ns frequenc	cy.				
Any oth	ner pati	ent o	bservatio	ns								

THYMOG	LOBULINE
(r-ATG	CHART

Paracetamol oral 1g Chlorphenamine oral 4mg Hydrocortisone iv 100mg Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.9%* Infuse over at least 6 hours via central line. r-ATG must be administered during core working	Patient	t's name:					S number:			Dat	e of bir	th:	
Paracetamol oral 1g print name Given Sign oral 1g	I th THYN	иодгов	ULINE	(r-ATG)	INFUSIO	N							
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Temp (°C) Oxygen saturation (%)	Pulse												
Oxygen saturation (%)	Respirat	ory rate											
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Any other patient observations						further	observation	ns frequency	' .				
Any other patient observations	Ally Oti	nei patie		/servatio									
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THYMOG	LOBULINE
(r-ATG	CHART

Paracetamol 1g	Patient	t's name	::				S number:				Date of bi	rth:	
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Chlorphenamine oral 4mg Hydrocortisone iv 100mg Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.9%* iv Infuse over at least 6 hours via central line. r-ATG must be administered during core working houpport measures are readily available due to its side-effect profile (including severe anaphylaxis). Start r-ATG 15 min 30 min 45 min 1 h 75 min 1.5 h 105 Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) 2.5 h 3 h 3.5 h 4 h 5 h 6 h 7 h 8 Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Date	Time	Pre	medicatio	on drugs	Route	e Dose	_				en by/Che Sign/Print	-
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Any other patient observations						further	observatio	ns freque	ncy.				
	Any ot	her pati	ient o	bservatio	ns								

THYMOG	LOBULINE
(r-ATG	CHART

Patient	t's name	:			S	number:			Date	of bi	rth:	
th THYN	/IOGLOI	BULIN	E (r-ATG)	INFUSIO	N							
Date	Time	Pre	medicatio	n drugs	Route	Dose	Signature print nan		ime iven	Given by/Cheo Sign/Print n		-
		Para	cetamol		oral	1g						
		Chlor	phenamir	ne	oral	4mg						
			ocortisone		iv	100mg						
Start AT	「G 1 hou	<u>r after</u>	administr	ation of pr	emedicat	tion drugs	•	1			1	
			ATG in 500 um chloric		iv							
				lable due t	o its side	e-effect pro	dministere	ing sev	ere ana	phyla	xis).	
			ATG	15 min	30 min	45 min	1 h	75 m	in :	1.5 h	105 min	2 h
Time												
ВР												
Pulse												
Respirat												
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Oxygen	saturatio	n (%)										
			2.5 h	3 h	3.5 h	4 h	5 h	6 h		7 h	8 h	9 h **
Time												
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Pulse												
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Oxygen	saturatio	n (%)										
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Any ot	her pati	ent o	bservatio	ns								

THYMOG	LOBULINE
(r-ATG	CHART

Date	IOGLOB Time	ULINI	F (r_ATG)									
Date	Time		L (I-AIG)	INFUSIO	N							
		Prei	medicatio	n drugs	Route	Dose	Signature, print nam		me /en	• •		-
		Parac	etamol		oral	1g						
		Chlor	phenamir	ne	oral	4mg						
		Hydro	ocortisone	2	iv	100mg						
Start AT	G 1 hour	after	administr	ation of pr	emedicat	tion drugs						
			ATG in 500 um chloric		iv							
upport m	neasures	are re	Start r-	lable due t	30 min	45 min	ofile (includi	ng seve		1.5 h	105 min	2 h
Time			AIG									
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Oxygen s	aturation	า (%)										
			2.5 h	3 h	3.5 h	4 h	5 h	6 h		7 h	8 h	9 h **
Time												
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TH	YMOG	LOBUL	.INE
(r-ATG	CHAR	Т

Patient	t's name:				S	number:			Date of	birth:			
th THYN	ИOGLOВ	ULIN	E (r-ATG)	INFUSIO	N								
Date	Time	Pre	medicatio	n drugs	Route	Dose	Signature print nam		me (•			
		Parac	cetamol		oral	1g							
		Chlor	phenamir	ne	oral	4mg							
<u> </u>			ocortisone		iv	100mg							
Start A7	ΓG 1 hour	after	administr	ation of pr	emedicat	tion drugs			1				
			ATG in 500 um chloric		iv								
							dministered				<u>rs</u> and	lite	
			ATG	15 min	30 min	45 min	1 h	75 mi	n 1.5	h 105 n	nin	2 h	
Time													
ВР													
Pulse													
Respirat	ory rate												
Temp (°	C)												
Oxygen	saturation	า (%)											
			2.5 h	3 h	3.5 h	4 h	5 h	6 h	7 h	8 h	9) h **	
Time													
ВР													
Pulse													
Respirat	ory rate												
Temp (°													
Oxygen	saturation	า (%)											
	w EWS ch her pati o				further o	bservation	ns frequenc	y.					
AIIY OL			osci vatio	113									

TH	YMOG	LOBUL	.INE
(r-ATG	CHAR	Т

Paracetamol oral 1g Chlorphenamine oral 4mg Hydrocortisone iv 100mg Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.99** Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours support measures are readily available due to its side-effect profile (including severe anaphylaxis).	Patient's name:						S number:			Date of birth:				
Name	th THYN	10GLOB	ULIN	E (r-ATG)	INFUSIO	N								
Chlorphenamine oral 4mg Hydrocortisone iv 100mg Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.99% iv sodium chloride	Date	Time	Pre	medicatio	n drugs	Route	Dose	•			Given by/Checked by Sign/Print name			
Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.9%* Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours upport measures are readily available due to its side-effect profile (including severe anaphylaxis). Start r			Para	cetamol		oral	1g							
Start ATG 1 hour after administration of premedication drugs r-ATG in 500mls of sodium chloride 0.9%* Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours support measures are readily available due to its side-effect profile (including severe anaphylaxis). Start r-ATG Start r-ATG I5 min 30 min 45 min 1 h 75 min 1.5 h 105 min Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) 2.5 h 3 h 3.5 h 4 h 5 h 6 h 7 h 8 h Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.			Chlo	phenamir	ıe	oral	4mg			_				
r-ATG in 500mls of sodium chloride 0.9%* Influse over at least 6 hours via central line. r-ATG must be administered during core working hours support measures are readily available due to its side-effect profile (including severe anaphylaxis). Start r			Hydr	ocortisone	•	iv	100mg							
Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours support measures are readily available due to its side-effect profile (including severe anaphylaxis). Start r-	Start AT	G 1 hour	after	administr	ation of pr	emedica	ation drugs							
Start r- ATG						iv								
Time BP Composition of the property o	upport n	neasures	are re	Start r-			· -	· 				105 mir	n 2 h	
Pulse Bespiratory rate Composition of the property of	Time			AIG										
Respiratory rate	ВР													
Temp (°C) Oxygen saturation (%) Oxygen	Pulse													
Oxygen saturation (%) 2.5 h 3 h 3.5 h 4 h 5 h 6 h 7 h 8 h Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Respirate	ory rate												
2.5 h 3 h 3.5 h 4 h 5 h 6 h 7 h 8 h Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Temp (°C	C)												
Time BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Oxygen s	saturation	ı (%)											
BP Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.				2.5 h	3 h	3.5 h	4 h	5 h	6 h		7 h	8 h	9 h **	
Pulse Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Time													
Respiratory rate Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	ВР													
Temp (°C) Oxygen saturation (%) **Follow EWS chart recommendations for further observations frequency.	Pulse													
**Follow EWS chart recommendations for further observations frequency.	Respirate	ory rate												
**Follow EWS chart recommendations for further observations frequency.	Temp (°C	C)												
	Oxygen s	saturation	ı (%)											
Any other patient observations						further	observation	s frequency	/ .					
	Ally Oti	lei patie												

TH	YMOG	LOBUL	.INE
(r-ATG	CHAR	Т

Patient	t's name	:			:	S number:			Dat	te of bir	th:		
LO th THYMOGLOBULINE (r-ATG) INFUSION													
Date	Time	Pre	Premedication drugs			Dose	Signature, print name						
		Parac	cetamol		oral	1g							
		Chlorphenamine			oral	4mg							
			ocortisone		iv	100mg							
Start AT	G 1 hou	r after	administr	ation of pr	<u>emedica</u>	tion drugs							
			ATG in 500 um chloric		iv								
* Infuse over at least 6 hours via central line. r-ATG must be administered during core working hours and life support measures are readily available due to its side-effect profile (including severe anaphylaxis).													
			Start r- ATG	15 min	30 min	45 min	1 h	75 min	١	1.5 h	105 n	nin	2 h
Time													
ВР													
Pulse													
Respirat	ory rate												
Temp (°	C)												
Oxygen :	saturatio	n (%)											
			2.5 h	3 h	3.5 h	4 h	5 h	6 h		7 h	8 h		9 h **
Time													
ВР													
Pulse													
Respirat													
Temp (°0													
Oxygen :	saturatio	n (%)											
**Follow EWS chart recommendations for further observations frequency. Any other patient observations													