All Wales PIMS-TS & Recovery Trial Pathway

Nov 2021

Noah's Ark Children's Hospital for Wales
Ysbyty Plant Cymru

This guide does not replace comprehensive work up of paediatric fevers
It only aids diagnosis, initial management and timeframes for PIMS-TS (and Recovery Trial Entry)
Suspected PIMS-TS requires early involvement of paediatric consult on call and MDT discussion

RCPCH case definition[1]

Is it PIMS-TS?

Use UK National management Consensus[2]

Child has persistent fever, inflammation (↑CRP/↑Neut/↓Lymph), single or multi-organ dysfunction (shock, cardiac, resp, GI, renal, neuro)

FBC, film CRP, ferritin, U/E, bone, LFT, amylase, CK, vit D, blood gas, lactate, clotting, fibrinogen, didimers, troponin, LDH, pro calcitonin & NTproBNP if available, and infection blood tests below

Prompt Infection Work up is crucial: blood culture, urine, LP discretionary, throat swab for COVID PCR and full viral respiratory screen and mc/s, COVID spike protein antibody serology, ASOT, VZV and EBV viral serology (not monospot), and other tests as clinically indicated. SAVE SERUM to Virology BEFORE IVIG.
CXR, ECG and early ECHO. ***EARLY ABDOMINAL U/S***

Assess Severity (shock, rising inflammatory markers, abnormal ECG or ECHO – see Appendix for full criteria

General Principles

PIMS TS diagnosis and treatment decisions including RECOVERY TRIAL are reached through early discussion with the MDT: Cardiology, Paeds ID via UHW switch +/- WATCh

Normal Supportive Care, Ceftriaxone (and clindamycin if shocked) pending cultures
Prophylactic Enoxiparin if significantly immobilised; if over 12 yrs, also wear compression stockings

Frequently re-assess, and also monitor mild cases closely (daily bloods)

PIMS -TS diagnosis agreed

	KAWASAKI under 5 yrs (don't wait 5 days) High Risk: coronary changes and/or age < 1 yr	PIMS-TS any age KAWASAKI-like over 5 yrs +/- Any cardiac dysfunction/low BP/shock
0-12 hours	**Early IVIG** (also overnight) **(if high risk : add Methyl Pred + PPI)**	**Methyl Pred (or IVIG) as per MDT discussion (consider Pred taper)**
0-12 hours	Aspirin: Kawasaki guidelines (d/w Cardiologist)	Aspirin: antiplatelet dose until ECHO normal 6/52

Closely monitor response (incl ECHOs), daily MDT discussion

Consider WATCh transfer (see criteria page 2)

24-48 hours	**Not improving: Methylpred, Pred taper, PPI**	**Not improving: Recovery Trial Tocilizumab/Anakinra/SOC**
96 hours	**Infliximab**	**Bespoke treatment as per MDT**

Discharge

Treat Vitamin D deficiency (per NICE guidance); Steroid card and advice if received ≥ 7 days
Open access for recurrences; Advise on pacing/graded exercise and review at 2 and 6 wks,6 and 12 months (as minimum).Referring consultant to report to BPSU please

On behalf of PIMS-TS MDT, Siske Struik, Consultant Paediatrician UHW Nov 2021, next review June 2022 or with trial amendments

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All Wales PIMS-TS & Recovery Trial Pathway June 2021
Key Points

Fever is common in, whilst PIMS -TS is very rare. The single most important challenge thus is to work through the potential causes of persistent fever in a timely manner.

RCPCH case definition of PIMS-TS [13]
A child (>44 weeks gestation) presenting with persistent fever, inflammation (neutrophilia, elevated CRP and lymphopenia) and evidence of single or multi-organ dysfunction (shock, cardiac, respiratory, renal, gastrointestinal or neurological disorder) with additional features. This may include children fulfilling full or partial criteria for Kawasaki disease. Exclusion of microbiological cause.

Making Diagnosis and Treatment Decisions
Every child with suspected PIMS-TS should be discussed with Paeds ID and Cardiology within 24 hours.
- Treatment for Kawasaki's disease follows standard of care, but is accelerated, especially in high risk groups. Do not hold up starting IVIG in clear cut Kawasaki's presenting out of hours.
- Note, Kawasaki's is rare children >5 years, and cardiac dysfunction/BP instability is not part of normal KD picture; both should prompt PIMS-TS MDT discussion.
- Best treatments for PIMS-TS (aka as 'non specific inflammatory phenotype) are being studied through Recovery Trial and BATS (data analysis in progress).

Severity Criteria (see also Appendix next page: panel 2 of national consensus document) [2]
Clinical deterioration, low BP (often whilst fully conscious), shock, worsening inflammatory markers (note ferritin), cardiac involvement.

Recovery trial – instructions (www.recoverytrial.net)
All Paediatric Units are strongly encouraged to recruit eligible patients rather than 'just treat'
Options change over time and decision to enrol requires Paediatric ID/MDT discussion (Or PICU)

Location of Care [15]
Determined by severity and cardiac status (or need for Tocilizumab/Anakinra)

How to contact UHW Paediatric COVID MDT (includes PIMS TS)
Core: Paediatric IMM/ID, Cardiology, PCCU, Respiratory (for chest) and other specialties as needed
Consultant to Consultant (ideally) via UHW Switch (Paeds ID no formal hours of hours cover – discuss with Gen Paeds on call consultant who can sign post to JE/SS or St Mary's Hospital if needed)

How to transfer to UHW (PICU, HDU or ward level)
Contact WATCh retrieval service 0300 0300 789. WATCh will include on a planning call with UHW:
- PICU consultant and Paediatric Cardiologist on call
- If ward to ward transfer, must also include the UHW General Paediatric Consultant on call
- Paediatric ID consultant on call can be included (optional, via switch)

Please note that depending on their capacity, WATCh may need to request the local team to transfer if felt clinically appropriate.

Surveillance and studies we participate in
BPSU, RECOVERY, ISARIC, pSep and BATS-study

Guideline for treatment of suspected and confirmed paediatric multisystem inflammatory syndrome temporally associated with COVID-19 (PIMS-TS)

Introduction

This document outlines the pharmacological treatment options for the management of suspected and confirmed paediatric multisystem inflammatory syndrome / hyper-inflammatory patients associated with COVID-19 (PIMS-TS)

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1	22nd May 2020	July 2020	15th May 2020
2	4th November 2020	January 2021	4th November 2020
3	June 2021	December 2021	June 2021
4	TBA	June 2022	November 2022

For information including definition, clinical management, monitoring and the general principles to treatment, refer to the UK National consensus document on PIMS-TS[13] and the RCPCH guidance entitled: COVID-19 Guidance on management of children admitted to hospital[15]

The following treatments are changing rapidly
Please ensure you are using the most up to date version of this guidance.

- Treatment must only be initiated once the MDT has been consulted.
- Consideration for enrolment into RECOVERY trial must be considered for all patients with suspected COVID-19 OR PIMS-TS, except those displaying a Kawasaki like presentation.
- Patients enrolled in the RECOVERY trial are advised to follow the doses as outlined in the trial document (which are the same as below).

TREATMENT

1. Intravenous antibiotics – do not delay.

   Clindamycin must only be prescribed if suspicion of toxic shock syndrome is present.

   Children under the age of 1 month: Cefotaxime, Amoxicillin and Clindamycin (See Paediatric Microguide)

   Children over the age of 1 month:
   Ceftriaxone
   Child 1 month–12 years: 80mg/kg IV once daily
   Child 12-18 years: 2-4g daily

   Clindamycin

Child 1 month–18 years: 10mg/kg (max 1.2g) qds IV in severe infections
Total daily dose may alternatively be given in 3 divided doses

Duration: Until Review by MDT

2. Human iv immunoglobulin (IVIG) – Must be prescribed by brand

Formulation: Choose brand based on the nearest vial size to limit wastage.

a. **IQYMUNE 100 mg/mL - 20ml (2g), 50ml (5g), 100ml (10g) and 200ml (20g)**

b. **INTRATECT 100 mg/ml –50ml (5g), 100ml (10g) and 200ml (20g)**

c. **PRIVIGEN 100mg/ml - 50ml (5g), 100ml (10g) and 200ml (20g)**

Supply permitting, otherwise any available product; wbs.wales/IVIg-SCIg-Product-Guide

Dose: 2g/kg - usually a single dose infusion, may be repeated according to clinical status. To avoid hyper viscosity, the second dose should be reduced to 1g/Kg if given within 48 hours of the first dose.

Use **ideal body weight** for patients who are overweight. (Appendix 1)
Notes: Indicated for all clinical presentations of PIMS-TS including Toxic Shock Syndrome, typical or atypical Kawasaki Disease +/- Myocarditis. Myocardial inflammation/coronary artery abnormalities.
Round down to closest whole vial size

Administration: Medusa

Procurement: Not stored in pharmacy, obtain from Blood Bank.

3. Steroids – On advice of Paediatric COVID MDT

Methylprednisolone – 1st line steroid (>corrected gestational age of 44 weeks)

Formulation: Injection as **sodium succinate**, 40mg, 500mg and 1g

Dose: 10mg/kg IV Once daily (up to 30mg/kg on advice of PIMS-TS Core MDT)

Maximum daily dose: 1g

Duration: 3 days without weaning (up to 5 days on advice of PIMS-TS Core MDT)

Monitoring: TPR and BP before the start and every 15 minutes during infusion.
Monitor urine sugar before and after infusion and 2 hours later.

Common side effects: Light-headed, dizzy, nauseous, or increasing headache.
- Action required: check TPR and BP and consider slowing or stopping the infusion. Inform the medical team.
Specific intervention required if:
• BP rises by >30mmHg (hypertension)
• BP falls accompanied by symptoms such as light-headedness
• Severe tachycardia (>150 bpm or patient feels palpitations or light-headed)
• Altered conscious state, seizures and psychosis
STOP infusion and obtain immediate medical review

Common mild side effects not requiring intervention: facial flushing, metallic taste, hyperactivity, mood changes.

Notes: Indicated for clinical presentations which include atypical Kawasaki Disease or persistent systemic inflammation following IVIG administration.
Aim to adjust doses to morning as soon as possible as interferes with sleep.
If multiple patients present aim for similar administration timings to enable vial sharing.

Prednisolone – (on advice from Paediatric COVID MDT)

Conversion: 5mg of prednisolone = 4mg of methylprednisolone.

Formulation: 5mg tablets

Dose: 2mg/kg in acute phase if IV access not available, round to nearest 5mg.

Max dose: 40mg (60mg may be used on Paediatric Rheumatology advice).

Weaning: Time frame and dose (usually 1mg/kg (max 40mg)) as directed by PIMS-TS Core MDT.

Adverse Effect: Gastritis - Max dose Lansoprazole must be prescribed alongside steroid treatment.

Lansoprazole

Body weight	Dose	Notes
>30kg	15-30mg daily in the morning	
15-30kg	15mg daily in the morning	
7.5-15kg	7.5mg daily in the morning	Use half 15mg FasTab
2.5-7.5kg	3.75mg daily in the morning	Use quarter of 15mg FasTab
<2.5kg	1mg/kg daily in the morning	

Administration – See "Lansoprazole in children - C&V Guideline for administration" located on INFORM under lansoprazole

4. Aspirin – (As per All Wales PIMS-TS Pathway)

Dose: 5mg/kg OD (Higher doses may only be used after discussion with cardiology).

Max dose: Weight: 15kg – 49kg = **75mg**
Weight: ≥50kg = **150mg**

Adverse effects: Gastritis – Max dose Lansoprazole must be prescribed alongside aspirin therapy.

Lansoprazole

Body weight	Dose	Notes
>30kg	15-30mg daily in the morning	
15-30kg	15mg daily in the morning	
7.5-15kg	7.5mg daily in the morning	Use half 15mg FasTab
2.5-7.5kg	3.75mg daily in the morning	Use quarter of 15mg FasTab
<2.5kg	1mg/kg daily in the morning	

Administration – See "Lansoprazole in children - C&V Guideline for administration" located on INFORM under lansoprazole

Duration: Until ECHO performed at 6-8 weeks and then reviewed.

Administration: 75mg soluble tablets, round to a measurable dose, fractions of tablets can be given.

5. VTE prophylaxis - On advice Paediatric COVID MDT

All children over 12 years of age should wear compression stockings until discharge home.

Prophylactic enoxaparin

The decision whether to give Enoxaparin is reached via discussion with the Paediatric COVID MDT.

Guiding principles:

Adults with COVID driven inflammation are at high risk of thrombosis and are given prophylaxis. The picture in children is not clear cut, and requires individualised consideration of risks of thrombosis versus the risks of enoxaparin (bleeding). Note that enhanced prophylactic dosing is no longer recommended.

For young people over the age 16 years, in principle you should follow adult guidelines on intranet

Indications to consider Enoxaparin

- older children/teenagers
- excess weight
- significant immobilisation
- significant inflammation (fever, inflammatory markers)
- central line
- pre-existing other pro-thrombotic conditions

Contraindications to Enoxaparin

Active bleeding/high risk of bleeding, lumbar puncture or epidural anaesthesia within the past 6h or due in the next 24h, severe hypertension over the 99th centile, thrombocytopenia: platelet count < 50 x 109 /L, acute bacterial endocarditis

For invasive procedures (LP or operations) must be >24hours off last dose before needle/knife to skin.

Prophylactic dose Enoxiparin as per cBNF

Children under the age of 1 month
750micrograms/kg twice daily (Round to the nearest mg for ease of administration)

Children over the age of 1 month – 16 years
500micrograms/kg twice daily. MAX: 40mg per day

If 101-150 kg: Enoxiparin 40 mg bd
If >150 kg: Enoxiparin 60 mg bd

Please note that with renal impairment eGFR should be calculated (below) and if under 30ml/min, dose adjustment is required. Discuss with hematology. As a guide, start with 50% of normal dose, and check levels 2-4 hrs after 3rd dose, aiming for anti Xa levels of 0.1 iu/dl.

Age	**Estimated eGFR equation** (mL/minute/ 1.73 m2)
Child over 1 year:	40 x height (cm)/serum creatinine (micromol/ litre)
Child between 1 month and 1 year:	35 x height (cm)/serum creatinine (micromol/ litre)
Neonate	30 x height (cm)/serum creatinine (micromol/ litre)

Treatment dose Enoxaparin as per cBNF

Indications: suspected pulmonary embolism, confirmed thromboembolism, or significant coronary artery aneurysm

If platelets <50 x10^9/L then discuss with paediatric haematology. As a guide: in first month of treatment support platelets with transfusion and keep above 50. Once out of first month then stop when platelets fall to < 50

For invasive procedures (LP or operations) must be >24hours off last dose before needle/knife to skin.

Refer to Paediatric Thrombosis and Anticoagulation Guidelines (2014) or Cardiology clinical guidelines (2019) for information on Dosage, Monitoring and Factor Xa Levels. Both can be found on the "Paediatric Cardiology" section of intranet

6. Immune Modulation Therapy – On advice of Paediatric COVID MDT only

The choice of agent will be decided on a case-by-case basis

- If features are of (atypical) Kawasaki picture then Infliximab would usually be first choice.
- In a non-specific inflammatory picture (PIMS-TS), if clinical equipoise, randomise to Tocilizumab or Anakinra or Standard of Care via **Recovery Trial**
- If features are suggestive of macrophage activation syndrome (MAS)/ sHLH picture then Anakinra would usually be first choice.

Infliximab (Inflectra) (TNFα)

Formulation: IV powder for reconstitution 100mg

Dose: 5-6mg/kg (rounded to the nearest vial size) on advice of PIMS-TS Core MDT

Duration: ONCE only – not to be repeated unless under cardiology advice

Administration: See MEDUSA

Notes: Hypersensitivity reactions reported during the infusion and up to 2 hours after. Ensure rescue medications are prescribed prior to administration:

Drug	Dose	Route
Chlorphenamine	6months – 6 years:2.5mg 6-12 years: 5mg 12-18 years: 10mg	IV
Paracetamol	15mg/kg/dose	PO
Hydrocortisone	6months – 6 years: 50mg 6-12 years: 100mg 12-18 years: 200mg	IV infusion (see medusa)

Anakinra (IL-1 Inhibitor)

Prescribe on drug chart only (no Trial form needed) and order via ward pharmacist (or on call pharmacist out of hours)

As part of Recovery Trial (exclude <1 year and/or <10 kgs)
Dose: 2mg/kg daily subcutaneous or IV for 7 days or discharge whichever is sooner

As part of suspected MAS/sHLH picture
Dose: 2-8 mg/kg daily subcutaneous or IV (max 600mg daily)

Choice of route as per discussion with MDT, considering:

- Intravenous achieves a higher and faster maximal plasma concentration (higher Cmax and shorter Tmax), compared with subcutaneous delivery.
- I/V route also preferred if:

- High doses (>2 mg/kg per day or >100 mg daily) required
- Platelets <20 × 109/L or haemorrhagic complications
- SC skin oedema
- Neurological symptoms

Also check BNFc for further adverse effects, monitoring requirements, cautions and contraindications.

Intravenous:

Formulation: 100mg in 0.67ml pre-filled syringes

Dose: I/V 2mg/kg BD increasing by 2mg/kg/day until response/max dose achieved

Max dose: IV 12mg/kg per day (6mg/kg BD) – **only to be used in PCCU** on advice of Paediatric Rheumatology/Immunology/Haematology Consultant.

Maximum daily dose: 400mg (i.e. 200mg per dose)

Administration: Dilute in a suitable volume of Sodium Chloride 0.9% and give as IV bolus over 3-5mins or add Anakinra dose to 50ml NaCl 0.9% before infusing intravenously, over 30 minutes.
Adverse effects: Headache; infection; neutropenia; thrombocytopenia
Cautions:
- confer an increased risk of infection, so careful assessment of co-infection should be made prior to use
- Ensure absolute neutrophil count is more than 1.5 x 10^9/litre
- Ensure **IL6 and soluble CD25 levels** are taken prior to use (if locally available)
- Duration depending on clinical response, review daily

Continuous Intravenous Infusion:

Continuous IV infusion is only to be used in patients who are critically unwell with significant oedema and capillary leak or unresponsive or has a contraindication to subcutaneous or IV bolus anakinra. **Only to be used in PCCU** on advice of Paediatric Rheumatology/Immunology/Haematology Consultant.

Change to subcutaneous administration as soon clinically appropriate.

Loading dose: 2mg/kg stat

Dose: 2mg/kg/day increasing by 2mg/kg/day every 12 hours if unresponsive to previous dose.

Max dose: 12mg/kg/day

Maximum daily dose: 400mg (excluding loading dose)

Administration (Via Syringe pump)

Weight	Concentration	Diluent	Starting rate of infusion (dose)
<20kg	100mg in **24ml** total volume	Sodium Chloride 0.9%	**0.02ml**/kg/hour (2mg/kg/hour)
>20kg	100mg in **12ml** total volume	Sodium Chloride 0.9%	**0.01ml**/kg/hour (2mg/kg/hour)

SYRINGE MUST BE CHANGED EVERY 8 HOURS

Compatibility: Anakinra should not be administered concomitantly via Y-site or mixed with any other medications due to lack of compatibility information.

Toculizumab (IL- 6 Inhibitor) via RECOVERY TRIAL

Intravenous
Age >1 year
<30kg 12mg/kg (a second dose may be given at ≥ 12 and ≥ 24 hours later under MDT discussion)
≥ 30 kg 8mg/kg (max 800mg) (a second dose may be given at ≥ 12 and ≥ 24 hours later under MDT discussion)

Administration (Via Syringe pump) **to be given over 1 hour**
CHILD less than 30kg:
Calculate the volume of tocilizumab concentrate required for the prescribed dose.
Remove the equivalent volume from a 50mL sodium chloride 0.9% infusion bag and discard.
Withdraw the dose from the vial(s) and add to the infusion bag.
Mix by gently inverting the infusion bag to avoid foaming.

CHILD 30kg and over:
Calculate the volume of tocilizumab concentrate required for the prescribed dose.
Remove the equivalent volume from a 100mL sodium chloride 0.9% infusion bag and discard.
Withdraw the dose from the vial(s) and add to the infusion bag.
Mix by gently inverting the infusion bag to avoid foaming.

Adverse effects: Hypersensitivity reactions including anaphylaxis, flushing, fever, chills, rash, pruritus, urticaria, headache, hypertension.
Monitor: Pulse, blood pressure, temperature & respiration rate for any signs of hypersensitivity reaction. Baseline observations should be measured after 15 minutes, then every 30 minutes until 1 hour post infusion.

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Appendix One – IBW

As there is no consensus on the best method or formula to use to calculate IBW, consistency in the method used is essential. The reverse BMI method (demonstrated below) is most preferable as it can be applied consistently to all children between 2 and 20 years.

BMI Method

The equation for BMI can be used in reverse to determine IBW:

IBW = BMI_{50} x height (m^2)

Where BMI_{50} represents the 50th centile of a BMI chart, which is the ideal BMI for their height, age and gender (4). BMI charts[i] are available from the Royal College of Paediatrics and Child Health website.

[i] Royal College of Paediatrics and Child Health. Body Mass Index (BMI) Chart [accessed 20/08/18]. Available from: https://www.rcpch.ac.uk/resources/body-mass-index-bmi-chart

Box 1: Example of IBW calculation using the BMI method

A 7 year old girl who is 1.2m tall

BMI_{50} = 15.6kg/m^2 (using Girls UK Body Mass Index 2-20 years chart)

IBW = BMI_{50} x height (m^2) = 15.6 x 1.2 x 1.2 = 22.5kg

CLINICAL TRIAL PRESCRIPTION

RANDOMISED EVALUATION OF COVID – 19 THERAPY (RECOVERY)

Paediatric Tocilizumab Prescription

Investigator: Prof Chris Fegan

Lead for Paediatrics: Dr Julian Forton

Patient details *(addressograph)*

Weight……kg

Patient Trial Number:…….

Ward……

Please dispense the following to the above patient:

Tocilizumab IV ……..mg

Dose determined by body weight:

Weight	Dose
Under 1 year of age	Excluded
< 30kg	12mg/kg
≥ 30 kg	8mg/kg (max dose 800mg)

- Based on vial size availability, doses can be rounded in accordance to the Roche dosing guide in order to minimise wastage and to allow doses to be measured accurately. Refer to page 7: https://www.medicines.org.uk/emc/rmm/1393/Document

Prescriber's Signature.....Date.....

Prescriber's Name……..Bleep/Ext.....

PHARMACY USE ONLY

Clinical Check**.....*****Date*****.....**

Dispensed by**.....*****Date*****.....**

Checked by**..... *****Date*****.....**

Please initial once complete:

Prescription signed and dated	Disp	Checker .....
Site Signature log signed and dated	Disp.....	Checker.....
Accountability Logs signed/dated	Disp	Checker.....